Exhibit 51

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 9
ELIZABETH A. HOLMES,	)	SEPTEMBER 21, 2021
DEFENDANT.	)	PAGES 1240 - 1449

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF:
UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:
IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

APPROXIMATELY?

A. IN THE BEGINNING OF 2014 I SAW HER FOR ROUTINE WOMEN'S WELLNESS, AND THEN IN THE SUMMER OF 2014 I SAW HER FOR A PREGNANCY LOSS, AND AGAIN IN SEPTEMBER OF 2014.

Q. YOU SAW HER AGAIN IN SEPTEMBER OF 2014?

A. FOR A SUBSEQUENT PREGNANCY.

Q. SO TELL US ABOUT THAT. WHAT WAS THE STATUS OF THINGS DURING THAT VISIT OF SEPTEMBER 2014?

A. UH-HUH. SO I SAW B[redacted]. SHE HAD HAD A POSITIVE PREGNANCY TEST AT HOME. SHE HAD HAD PREVIOUS MISCARRIAGES, AND SO THAT VISIT WAS EARLY ON IN THE PREGNANCY AS SHE WAS WANTING TO ESTABLISH CARE EARLY, AND I WAS WANTING TO GIVE REASSURANCE TO HER AND TO US OF THE WELL BEING OF HER PREGNANCY.

SO IT WAS A VISIT TO ESTABLISH, YES, SHE IS PREGNANT, AND TO LOOK AT THE HEALTH OF THE PREGNANCY.

Q. AND DID THIS PATIENT'S PARTICULAR HISTORY THAT YOU MENTIONED PLAY INTO THE DECISIONS THAT YOU MADE SUBSEQUENTLY ABOUT HOW TO APPROACH THE EARLY STAGE OF THE PREGNANCY?

A. ABSOLUTELY. SO SHE HAD HAD THREE MISCARRIAGES PRIOR TO OUR VISIT IN SEPTEMBER, AND IN OBSTETRICS THAT'S CONSIDERED INCURRED PREGNANCY LOSS, WHICH THAT PUTS HER INTO A HIGH RISK PREGNANCY CATEGORY, SO WE FOLLOW THOSE PREGNANCIES MORE CLOSELY, PARTICULARLY IN EARLY PREGNANCY WHERE WE WERE DRAW SERUM QUANTS TO LOOK AT THE HEALTH OF THE PREGNANCY, AN HCG QUANT.

01:31PM Q. IS THIS WHAT YOU WERE EXPECTING TO SEE BASED ON THE THERANOS RESULTS?

01:31PM A. NO.

01:31PM Q. AND EXPLAIN WHY NOT?

01:31PM A. THERE ISN'T A MEDICAL EXPLANATION IN A PREGNANCY LOSS FOR THE VALUE TO GO FROM THE HUNDREDS WAY BACK INTO THE THOUSANDS OR TO GO UP AT ALL REALLY.

01:32PM Q. THE FOLLOWING RESULT WAS ANOTHER TWO DAYS LATER; IS THAT CORRECT?

01:32PM A. THAT'S CORRECT.

01:32PM Q. ON OCTOBER 8TH, 2014, DID SONORA QUEST PROVIDE ANOTHER HCG VALUE FOR MS. [redacted]?

01:32PM A. THEY DID.

01:32PM Q. AND WHAT WAS THAT VALUE?

01:32PM A. 17,716.

01:32PM Q. AND LOOKING AT THOSE LAST TWO SONORA QUEST VALUES, WHAT DID THEY SIGNAL TO YOU AS A MEDICAL PROFESSIONAL?

01:32PM A. SO THAT'S A MERE DOUBLE WITHIN 48 HOURS SUGGESTING THAT THE PREGNANCY IS MOVING IN A VIABLE WAY.

01:32PM Q. AND I THINK YOU TESTIFIED EARLIER THAT WE KNOW THIS STORY HAS A HAPPY ENDING AND MS. G[redacted] CARRIED HER PREGNANCY TO TERM?

01:32PM A. YES.

01:32PM Q. AND BASED ON THAT INFORMATION, DID YOU REACH A CONCLUSION ABOUT THE ACCURACY OF THE THERANOS TEST RESULTS?

01:33PM A. I FELT VERY UNCERTAIN OF THE VALIDITY OF THE RESULTS AND

CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

Irene Rodriguez

IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076

Lee-Anne Shortridge

LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: SEPTEMBER 21, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 10
ELIZABETH A. HOLMES,	)	SEPTEMBER 22, 2021
DEFENDANT.	)	PAGES 1450 - 1685

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF:
UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
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(APPEARANCES CONTINUED ON THE NEXT PAGE.)

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PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

11:01AM THE TRUTH. IT'S OFFERED FOR NOTICE.

11:01AM THE SECOND LINE IS A STATEMENT BY AN AGENT UNDER

11:01AM 801(D)(2)(E), AND IT IS OFFERED FOR THE TRUTH.

11:01AM MS. TREFZ: I DON'T BELIEVE THIS MESSAGE HAS BEEN

11:01AM IDENTIFIED UNDER THE LOCAL RULES AS AN 801(D)(2) STATEMENT.

11:01AM THE COURT: IS THERE ANY FOUNDATION FOR THE

11:01AM INDIVIDUAL THAT IS LISTED HERE? BECAUSE I'M NOT SURE I HAVE

11:01AM THAT.

11:01AM MR. LEACH: IN THE FIRST SENTENCE, YOUR HONOR?

11:01AM THE COURT: YES. FOR AGENCY PURPOSES, I'M NOT

11:01AM CERTAIN THERE'S A FOUNDATION FOR THAT.

11:01AM MR. LEACH: I'M OFFERING THAT FIRST LINE FOR NOTICE,

11:01AM NOT -- FOR A NONHEARSAY PURPOSE.

11:01AM THE SECOND LINE IS NOT CONNECTED TO THAT FIRST PERSON.

11:02AM THE COURT: I THINK THE 805 GOES TO THE SECOND, THE

11:02AM SECOND LINE, THE COMMENT THAT THERE IS --

11:02AM MR. LEACH: I THINK THAT'S A COMMENT BY THE SENDER

11:02AM OF THE MESSAGE, YOUR HONOR.

11:02AM (PAUSE IN PROCEEDINGS.)

11:02AM THE COURT: ALL RIGHT. THE FIRST LINE YOU'RE ASKING

11:02AM TO BE ADMITTED PURELY FOR NOTICE AS TO MS. HOLMES ONLY?

11:02AM MR. LEACH: YES.

11:02AM THE COURT: AND NOTICE OF WHAT SPECIFIC ISSUE?

11:03AM MR. LEACH: KNOWLEDGE OF THE MEDIA, PERCEPTION OF

11:03AM THE COMPANY, HOW CERTAIN MESSAGES ARE GETTING ACROSS.

CERTIFICATE OF REPORTERS

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CERTIFICATE NUMBER 9595

DATED: SEPTEMBER 22, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 18
ELIZABETH A. HOLMES,	)	OCTOBER 13, 2021
DEFENDANT.	)	PAGES 3279 - 3537
_____	)	**PAGES 3292 - 3364 SEALED**
		PAGES 3534 - 3537 SEALED

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11:59AM LISTED, THAT MAYBE WE WEREN'T TRAINING PEOPLE FAST ENOUGH
11:59AM PROPERLY, MAYBE WE WEREN'T GETTING OUR EXPERIENCE RIGHT FAST
11:59AM ENOUGH.
11:59AM Q. THANK YOU.
11:59AM WOULD YOU NOW TURN TO EXHIBIT 1254.
11:59AM WHAT IS THIS DOCUMENT?
11:59AM A. I BELIEVE THIS IS AN EMAIL THAT FORWARDS AN ARTICLE ON
11:59AM THERANOS.
11:59AM Q. FIRST AN EMAIL FROM MR. BALWANI TO FOLKS AT WALGREENS AND
11:59AM THEN FROM MR. -- DR. ROSAN AT WALGREENS TO YOU; IS THAT RIGHT?
11:59AM A. THAT'S CORRECT. THAT'S RIGHT.
12:00PM MR. SCHENK: YOUR HONOR, THE GOVERNMENT OFFERS 1254.
12:00PM MR. DOWNEY: YOUR HONOR, I DON'T OBJECT TO THE
12:00PM EMAIL, BUT THE ARTICLE CONTAINS A GOOD AMOUNT OF HEARSAY, THE
12:00PM ATTACHMENT.
12:00PM MR. SCHENK: YOUR HONOR, I'M CERTAINLY NOT OFFERING
12:00PM THE ARTICLE FOR ITS TRUTH.
12:00PM THE COURT: IT'S BEING OFFERED FOR WHAT PURPOSE?
12:00PM MR. SCHENK: I'M SORRY?
12:00PM THE COURT: WHAT PURPOSE?
12:00PM MR. SCHENK: TO SHOW THE STATE OF MIND OF THE
12:00PM INDIVIDUAL WHO SENT IT. I THINK IT'S ALSO 801(D)(2)(E).
12:00PM THE COURT: ALL RIGHT. I'LL ADMIT THIS.
12:00PM LADIES AND GENTLEMEN, THE ARTICLE THAT YOU'LL SEE IN JUST
12:00PM A MOMENT IS NOT BEING OFFERED FOR THE TRUTH OF THE MATTER

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DATED: OCTOBER 13, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 36
ELIZABETH A. HOLMES,	)	NOVEMBER 2, 2021
DEFENDANT.	)	PAGES 4903 - 5186

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

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AND WAG?

A. YES.

Q. AND IN YOUR EXPERIENCE, IS WAG AN ACRONYM FOR WALGREENS?

A. YES.

Q. AND THE DATE OF THIS IS OCTOBER 10TH, 2014.

IS THAT IN THE MONTH WHEN, WHEN RDV WAS CONSIDERING AN INVESTMENT DECISION?

A. YES.

MR. LEACH: YOUR HONOR, I OFFER EXHIBIT 2065 INTO EVIDENCE.

MR. WADE: YOUR HONOR, I DON'T SEE ANY FOUNDATION OR RELEVANCE TO THIS DOCUMENT FROM THIS WITNESS, AND HEARSAY.

(PAUSE IN PROCEEDINGS.)

THE COURT: CAN YOU LAY A LITTLE MORE FOUNDATION ON THIS, AND TELL ME HOW IT RELATES TO THE REDIRECT AGAIN.

MR. LEACH: YOUR HONOR, THIS WITNESS WAS ASKED QUESTIONS ABOUT WHETHER OR NOT RDV VISITED A WALGREENS IN THIS TIME PERIOD. THIS RELATES TO ANOTHER POTENTIAL INVESTOR IN THE SAME TIME PERIOD.

IT'S NOT HEARSAY BECAUSE IT'S A STATEMENT OF AN AGENT.

IT'S ALSO 801(D)(2)(E), AND I THINK MR. EDLIN LAID A FOUNDATION UNDER THE BUSINESS RECORD EXCEPTION.

I ALSO OFFER IT FOR THE NONHEARSAY PURPOSE FOR STATE OF MIND TO THE RECIPIENT.

AND IT RELATES TO -- THE QUESTIONS WERE ASKED ABOUT THE

SHOWN SUCH THAT STATEMENTS CAN BE ENTERED.

I THINK THIS IS THE FIRST TIME THAT THAT HAS COME UP IN THE TRIAL WHERE, MR. LEACH, YOU MENTIONED IT COULD COME IN AS A STATEMENT OF A COCONSPIRATOR IN FURTHERANCE OF UNDER 801(D)(2)(E).

I'VE TAKEN NOTES. I DON'T KNOW IF YOU WANT TO KNOW MY OPINION ABOUT IT. IT SEEMS TO ME THAT THERE HAS BEEN AT LEAST FOR PRIMA FACIE SHOWING, IT SEEMS LIKE SOME OF THE STATEMENTS AND THE EVIDENCE THAT HAS COME IN DOES ESTABLISH AT LEAST FOR EVIDENTIARY PURPOSES A PRIMA FACIE CASE.

I DON'T KNOW IF YOU WANT TO COMMENT. I'M NOT TRYING TO TAKE US DOWN A SIDE ROAD BUT --

MR. WADE: I'D LIKE TO ADDRESS THAT MORE THOUGHTFULLY, FRANKLY, YOUR HONOR, RATHER THAN DOING IT ON THE FLY WITH RESPECT TO THIS ISSUE.

OF COURSE, THERE'S A NOTICE CONCERN THAT COMES WITH 801(D)(2)(E) --

THE COURT: RIGHT.

MR. WADE: -- THAT THE NORTHERN DISTRICT TAKES VERY SERIOUSLY, AND I KNOW THE COURT DOES AS WELL. THIS WAS NOT NOTICED UNDER 801(D)(2)(E), AND THAT IS NOW ALSO A REQUIREMENT UNDER THE FEDERAL RULES OF EVIDENCE. THEY ACTUALLY -- THE NORTHERN DISTRICT WAS ACTUALLY A LITTLE IN FRONT OF THE RULES COMMITTEE ON THAT.

SO I THINK IT WOULD BE UNFAIR TO CONCLUDE ON THIS WITHOUT

11:51AM NOTICE. ARGUABLY IT'S EXCLUDABLE AS OFFERED UNDER THAT AS A
11:51AM RESULT OF THE LACK OF NOTICE, BUT AT A MINIMUM, I WOULD LIKE TO
11:51AM HAVE THE OPPORTUNITY TO ADDRESS THAT.
11:51AM AGAIN, THIS WITNESS OFFERS NO TESTIMONY ON THIS. BDT WAS
11:51AM ADDRESSED, BUT IT WASN'T ADDRESSED IN CONNECTION WITH
11:51AM WALGREENS. IT WAS ADDRESSED IN CONNECTION WITH A CONFERENCE.
11:51AM SHE DIDN'T HAVE ANY INTERACTIONS OR KNOWLEDGE OF BDT APART FROM
11:51AM WHAT MR. LEACH JUST PULLED OUT ON REDIRECT, WHICH HE CAN'T OPEN
11:51AM HIS OWN DOOR.
11:51AM I ASKED QUESTIONS ABOUT WHETHER SHE HAD INTERACTIONS WITH
11:51AM BDT OR WHETHER SHE KNEW ABOUT INTERACTIONS, WHETHER SHE WAS
11:51AM THERE, AND HER ANSWER UNDER ALL OF THAT WAS NO.
11:51AM SO I THINK IT'S A HUGE STRETCH TO PUT THIS IN. IT DOESN'T
11:51AM NEED TO COME IN NOW. I'D LIKE THE OPPORTUNITY TO, YOU KNOW, TO
11:51AM CONSIDER THIS AND ADDRESS THIS OUTSIDE OF THE CONTEXT GIVEN
11:51AM THAT WE DIDN'T GET NOTICE AND IT'S BEING OFFERED AS A
11:51AM COCONSPIRATOR EXCEPTION.
11:51AM THE COURT: WELL, AMONGST OTHERS, BUT THERE ARE
11:51AM OTHER REASONS WHY MR. LEACH PROFFERS THIS. HE DID OFFER IT FOR
11:51AM THAT PURPOSE.
11:51AM BUT I DO -- I SEE SOME RELEVANCE AS TO THIS. WHETHER OR
11:51AM NOT TIMING IS APPROPRIATE NOW TO INTRODUCE IT -- YOU KNOW,
11:51AM MR. LEACH, I'M GOING TO SUSTAIN THE OBJECTION AS TO THIS
11:51AM WITNESS. I JUST DON'T THINK THE TIMING IS RIGHT AND THE
11:51AM FOUNDATION IS THERE TO GET THIS IN NOW.

I MADE MY COMMENTS ABOUT AT LEAST GENERALLY FINDING THE EVIDENCE SHOWS BASED UPON TEXT MESSAGES, AND I DON'T HAVE ALL OF MY NOTES HERE, BUT I'VE MADE NOTES ABOUT ASPECTS OF CONVERSATIONS AND OTHERS THAT COULD SHOW A PRIMA FACIE CASE OF A CONSPIRACY IN FURTHERANCE OF DURING THE CHARGING PERIOD, WHICH WOULD THEN OPEN THE DOOR FOR OTHER HEARSAY STATEMENT OR OTHER STATEMENTS OF THE PARTIES. I JUST WANT TO LET YOU KNOW THAT, AND I'M DOING THIS OUTSIDE OF THE PRESENCE OF THE JURY, OF COURSE, JUST TO KEEP YOU APPRISED OF THAT.

BUT ALL OF THE NOTICE AND ALL OF THE OTHER RULES, OF COURSE, APPLY.

BUT SINCE YOU RAISED IT, MR. LEACH, TALKING ABOUT THIS, I THOUGHT I WOULD GIVE YOU AT LEAST THE BENEFIT OF MY THOUGHTS ON THAT, RIGHT OR WRONG, BUT I JUST WANTED TO SHARE THAT WITH YOU.

MR. LEACH: THANK YOU, YOUR HONOR.

THE COURT: SO YOU CAN EXPLORE BDT. IT WAS TALKED ABOUT.

I JUST THINK GETTING THE DOCUMENT IN NOW THROUGH THIS WITNESS IS NOT APPROPRIATE AT THIS TIME.

SO AT THIS TIME I'LL SUSTAIN THE OBJECTION. I'LL DO IT OUT THERE IN FRONT OF THE JURY.

MR. LEACH: OKAY.

MR. WADE: OKAY. THANK YOU, YOUR HONOR.

MR. LEACH: THANK YOU, YOUR HONOR.

(END OF DISCUSSION AT SIDE-BAR.)

CERTIFICATE OF REPORTER

I, THE UNDERSIGNED OFFICIAL COURT REPORTER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

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CERTIFICATE NUMBER 8074

DATED: NOVEMBER 2, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 30
ELIZABETH A. HOLMES,	)	NOVEMBER 9, 2021
DEFENDANT.	)	PAGES 5671 - 5872

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UNITED STATES DISTRICT JUDGE

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PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

02:14PM A. THAT'S CORRECT.
Q. AND IN NUMBER 2 IT SAYS, "THE TOTAL PERCENTAGE OF QC VALUES GREATER THAN 2 STANDARD DEVIATIONS (SDS) WAS REVIEWED BY THE SURVEYOR."
DO YOU SEE THAT LANGUAGE?
A. I DO.
Q. AND DO YOU UNDERSTAND WHAT IS MEANT BY "STANDARD DEVIATIONS"?
A. YES, I DO.
Q. AND WHAT IS A STANDARD DEVIATION?
A. WOULD YOU LIKE THE MORE TECHNICAL DEFINITION?
Q. I'D LIKE THE LESS TECHNICAL DEFINITION IF YOU COULD.
A. IT'S, IN GENERAL, AN ESTIMATE OF THE SPREAD OF A DATA SET, HOW WIDELY THE VALUES VARY.
Q. OKAY.
A. IN LABORATORY PARLANCE, WE USE IT TO ESTIMATE PRECISION.
Q. AND IF WE CAN GO TO THE NEXT PAGE, PLEASE, PAGE 56.
DR. DAS, DO SOME OF THE CMS FINDINGS CONTINUE -- WITH RESPECT TO THIS D TAG CONTINUE ON TO THE NEXT PAGE?
A. YES, I SEE THAT.
Q. OKAY. DO YOU SEE WHERE IT SAYS, "IN JULY 2014, THE DATA REVEALED THE FOLLOWING TESTS SHOWED PERCENTAGE OF QC SAMPLES WITH MORE THAN 15 PERCENT OF VALUES GREATER THAN 2 SD." AND THEN THERE'S TESTOSTERONE, TOTAL T4, VITAMIN D.
"OVERALL 16 PERCENT OF QC SAMPLES ON ALL TESTS ON ALL

DEVICES HAD VALUES GREATER THAN 2 SDS."

DO YOU SEE THAT LANGUAGE?

A. I DO SEE THAT.

Q. OKAY. AND WERE TST, TOTAL T4, AND VITAMIN D ASSAYS RUN ON THE EDISON IN THE 2014 TIME PERIOD?

A. THAT IS CORRECT. I BELIEVE THAT'S WHAT THEY'RE REFERRING TO.

Q. AND DID YOU AND YOUR TEAM ALSO REVIEW THE DATA THAT IS LISTED HERE ON THIS FORM?

A. YES.

Q. AND DID YOU REVIEW AN EVEN BROADER UNIVERSE OF QC DATA IN ORDER TO RESPOND TO THE CMS REPORT?

A. WE DID.

Q. AND IS THIS -- IS THE FINDING LISTED HERE CONSISTENT WITH WHAT YOU REVIEWED IN YOUR REVIEW OF DATA?

MR. WADE: YOUR HONOR, 702 ON THIS ISSUE, PARTICULARLY GIVEN THE PURPOSE THAT THIS EVIDENCE HAS BEEN OFFERED.

THE COURT: MR. LEACH, I THINK YOU'RE ON THE MARGINS OF A 702 AREA, SO LET ME ASK YOU TO REPHRASE YOUR QUESTION.

BY MR. LEACH:

Q. DID YOU ALSO -- DID YOU ALSO REVIEW THE DATA THAT IS LISTED IN THIS REPORT, IN THIS PARAGRAPH E, DR. DAS?

A. I DON'T RECALL THESE EXACT NUMBERS, BUT THESE TIME FRAMES ARE CONSISTENT WITH MY RECOLLECTION.

02:17PM Q. OKAY. AND IN RESPONDING TO CMS, DID -- OR YOU NEEDED TO FORMULATE A RESPONSE TO CMS ON BEHALF OF THE COMPANY; IS THAT CORRECT?

02:17PM A. YES, THAT IS CORRECT.

02:17PM Q. AND DID YOU LOOK AT NOT JUST DATA FOR JULY OF 2014, BUT A BROADER UNIVERSE OF DATA IN ORDER TO UNDERSTAND AND RESPOND TO CMS?

02:17PM A. YES, WE DID.

02:17PM Q. OKAY. AT ANY POINT DID YOU TELL CMS THAT THE COMPANY DISAGREED WITH THIS PARTICULAR FINDING?

02:17PM A. NO, I DON'T BELIEVE WE DID.

02:17PM Q. OKAY. WHY NOT?

02:17PM A. THESE FINDINGS --

02:17PM MR. WADE: YOUR HONOR, AGAIN, 702. WE'RE JUST USING REVERSE INSTEAD OF FORWARD.

02:17PM THE COURT: I UNDERSTAND.

02:17PM I THINK YOU'RE ASKING FOR AN OPINION THAT FALLS UNDER 702 THE WAY THE QUESTION IS FORMED, SO I'LL SUSTAIN THE OBJECTION.

02:17PM BY MR. LEACH:

02:17PM Q. BUT YOU NEVER SAID TO ANYBODY AT CMS, "I DISAGREE WITH THIS FINDING"?

02:18PM A. I DON'T RECALL SAYING THAT OR WRITING THAT.

02:18PM Q. LET'S GO TO NUMBER F.

02:18PM A. OKAY.

02:18PM Q. AND IF WE CAN ENLARGE THAT, MS. HOLLIMAN.

I'M SORRY. I THINK WE'RE DOWN ON H. I WANTED TO FOCUS ON F IF WE COULD:

THIS READS, DR. DAS, "IN OCTOBER 2014 THE DATA REVEALED THE FOLLOWING TESTS SHOWED PERCENTAGE OF QC SAMPLES WITH MORE THAN 15 PERCENT OF VALUES GREATER THAN 2 SD."

DO YOU SEE THAT LANGUAGE?

A. I DO.

Q. AND THEN THERE'S A LIST FOR ESTRADIOL, FREE T4, PROLACTIN, SHBG, TSH, TST, TOTAL T3, TT4, VITAMIN D, AND VITAMIN B12.

DO YOU SEE THOSE?

A. I DO.

Q. AND ARE ALL OF THOSE ASSAYS THAT WERE RUN ON THE EDISON?

A. YES.

Q. AND AS A LAB DIRECTOR, IS IT DESIRABLE OR UNDESIRABLE TO HAVE A CV OF GREATER THAN 15 PERCENT?

A. THAT WOULD BE UNDESIRABLE.

Q. THIS SAYS, "OVERALL 29 PERCENT OF QC SAMPLES ON ALL TESTS ON ALL DEVICES HAD VALUES GREATER THAN 2 SD'S."

DO YOU SEE THAT?

A. YES, I SEE THAT.

Q. AND WHAT DID YOU UNDERSTAND THAT TO MEAN?

A. THAT -- I UNDERSTAND THAT TO MEAN THAT 15 PERCENT OF THE VALUES WERE VIOLATING THE 2 SD RULE, WHICH IS A COMMON QUALITY CONTROL RULE.

Q. AND DID YOU HAVE DISCUSSIONS WITH MS. HOLMES ABOUT THIS

QUALITY CONTROL RULE AND THE DATA THAT WAS BEING REPORTED BY CMS?

A. IN GENERAL, YES.

Q. LET'S GO TO LETTER G.

DO YOU SEE WHERE IT SAYS, "IN FEBRUARY OF 2015, THE DATA" -- OH, BEFORE I LEAVE G, DID YOU EVER TELL CMS THAT YOU DISAGREED WITH THIS FINDING IN F?

MR. WADE: YOUR HONOR, I'M GOING TO OBJECT ON 702 GROUNDS TO THIS AS WELL.

THE COURT: OVERRULED. YOU CAN ANSWER THE QUESTION.

THE WITNESS: NO, I DO NOT RECALL THAT.

BY MR. LEACH:

Q. IN G IT SAYS, "IN FEBRUARY 2015, THE DATA REVEALED THE FOLLOWING TESTS SHOWED THE PERCENTAGE OF QC SAMPLES WITH MORE THAN 15 PERCENT OF VALUES GREATER THAN 2 SD."

AND IT LISTS FT4, SHBG, TT3, VITAMIN D, VITAMIN B12.

DO YOU SEE THAT?

A. I DO.

Q. AND THOSE ARE TESTS THAT ARE RUN ON EDISON?

A. THAT IS CORRECT.

Q. AND AT ANY POINT IN TIME DID YOU TELL CMS THAT YOU DISAGREED WITH THIS FINDING?

A. NO, I DON'T RECALL DOING SO.

Q. LET'S LOOK AT H AND I.

DO YOU SEE WHERE IT SAYS, "IN MARCH OF 2015, THE DATA

TIME PERIODS (ACROSS ALL ANALYTES TESTED) OF ABRUPT SHIFTS IN QC TARGET MEANS."

WHAT DOES THAT MEAN?

A. PLEASE GIVE A MINUTE TO REVIEW THAT.

(PAUSE IN PROCEEDINGS.)

THE WITNESS: SO THAT FIRST PART MEANS THAT THE AVERAGE VALUES OF QUALITY CONTROL, THE TARGETS THAT WE WERE TRYING TO REACH, OR THAT THE LABORATORY WAS TARGETING, WERE BEING SHIFTED UNEXPLAINEDLY.

BY MR. LEACH:

Q. "HIGH RATES OF 1-2S QC RULE FAILURES."

WHAT IS MEANT BY "1-2S"?

A. SO THIS 1-2S ACTUALLY REFERS TO THE SAME QC RULE FAILURES THAT THE CMS INSPECTORS WERE NOTING IN THAT D TAG. I BELIEVE IT WAS 5791, I BELIEVE. SO THEY CALL IT A --

Q. AND THE 1-2S, THAT'S STANDARD DEVIATIONS?

A. YES. SO THE 2S REFERS TO 2 SD ANALOGOUS TO WHAT IS BEING REFERRED TO IN THE D TAG.

Q. AND "QC CV'S FAR EXCEEDING LIMITS FOR A STABLE TESTING PROCESS."

WHAT DID THAT MEAN?

A. TO SIMPLIFY THAT ONE A BIT, IT JUST MEANS THAT THERE WAS A LOT OF IMPRECISION NOTED.

Q. AND IS IMPRECISION DESIRABLE OR UNDESIRABLE?

A. UNDESIRABLE.

REVIEWED FROM JUNE 2014 THROUGH NOVEMBER 2014 AND JANUARY THROUGH FEBRUARY 2015 FOR VITAMIN B12, VITAMIN D, AND SEX HORMONE BINDING GLOBULIN WHICH WERE USED FOR PATIENT TESTING ON THE TPS DEVICES."

DO YOU SEE THAT LANGUAGE?

A. YES.

Q. AND IS THIS ALSO DATA THAT YOU REVIEWED IN THE COURSE OF YOUR WORK?

A. YES.

Q. IN C IT SAYS, "VITAMIN B12 QC LEVEL 1 AND LEVEL 3 ON DEVICE E 110 REVEALED THE FOLLOWING PERCENT CV: 34.3 PERCENT AND 48.5 PERCENT RESPECTIVELY FROM JANUARY 5TH, '15 THROUGH 1-30-15."

DO YOU SEE THAT LANGUAGE?

A. YES.

Q. AND THE DEVICE E 110, DID YOU UNDERSTAND THAT TO REFER TO A PARTICULAR EDISON DEVICE WITHIN THE LAB? DID YOU UNDERSTAND THAT TO REFER TO A DEVICE WITHIN THE LAB?

A. YES.

Q. AND THE QC LEVEL 1 AND LEVEL 3, WHAT DID YOU UNDERSTAND THOSE TO REFER TO?

A. THOSE ARE DIFFERENT LEVELS OF THE RESPECTIVE TEST QC, IN THIS CASE VITAMIN B12.

Q. AND CAN YOU -- AND WHAT IS THE PURPOSE OF DIFFERENT LEVELS?

03:29PM A. A LABORATORY IS REQUIRED TO RUN MULTIPLE LEVELS FOR EVERY QUANTITATIVE TEST, SO --

03:29PM Q. SO A HIGH LEVEL, A LOW LEVEL, SOMETHING IN BETWEEN?

03:29PM A. CORRECT.

03:29PM Q. OKAY. AND THIS SAYS THE QC LEVEL 1 AND 3 WERE 34.3 AND 48.5 PERCENT.

03:29PM WHAT WAS -- WHAT DID YOU UNDERSTAND THAT TO MEAN?

03:30PM A. IT APPEARS THEY'RE REFERENCING THOSE PARTICULAR LEVELS FOR THOSE QC.

03:30PM Q. AND ARE THESE DESIRABLE LEVELS OF QC OR UNDESIRABLE LEVELS OF QC?

03:30PM A. THOSE WOULD BE UNDESIRABLE.

03:30PM Q. AND IS THIS SOMETHING THAT YOU LOOKED INTO AS THE LABORATORY DIRECTOR?

03:30PM A. YES.

03:30PM Q. AND IF WE COULD ZOOM IN.

03:30PM IN D THERE'S SOME REFERENCE TO VITAMIN B12, QC1, AND QC3 ON DEVICE E 1085.

03:30PM IS THIS SIMILAR INFORMATION RELATING TO A DIFFERENT EDISON DEVICE THAT WAS BEING USED IN THE CLIA LAB?

03:30PM A. YES.

03:30PM Q. AND IS THAT SOMETHING THAT YOU INVESTIGATED?

03:30PM A. YES.

03:30PM Q. IF WE CAN ZOOM OUT, MS. HOLLIMAN, AND LOOK AT E THROUGH L, OR E THROUGH LITTLE I.

03:39PM Q. AND DID --

MR. WADE: YOUR HONOR, PARDON ME. JUST MOVE TO STRIKE ON 702 GROUNDS.

THE COURT: I'M GOING TO SUSTAIN THE OBJECTION. AND THAT LAST PORTION IS STRICKEN, LADIES AND GENTLEMEN.

BY MR. LEACH:

Q. DID YOU -- IN COMMUNICATING TO CMS, DID YOU DESCRIBE THE BASES -- DID YOU TELL CMS THAT THERANOS WAS VOIDING PT INR TESTS?

A. YES.

Q. AND DID YOU EXPLAIN TO THEM WHY THERANOS WAS DOING THAT?

A. YES.

Q. WHAT DID YOU TELL CMS?

A. I DO NOT RECALL THE EXACT LANGUAGE, BUT IT REFLECTED THE INACCURATE CALCULATIONS, AS WELL AS QUALITY CONTROL ISSUES AND INACCURACIES REFLECTED IN THE PATIENT TEST RESULT DISTRIBUTIONS.

Q. LET'S GO FURTHER IN TIME IN THIS DOCUMENT TO PAGE 41. IF WE CAN HIGHLIGHT D THROUGH H -- OR ACTUALLY D THROUGH I. I'M SORRY, MS. HOLLIMAN.

DO YOU SEE, DR. DAS, IN D WHERE IT SAYS, "ON SEPTEMBER 7TH, 2015, CITROL 3 WAS RUN SEVEN TIMES WITHOUT OBTAINING AN ACCEPTABLE QC VALUE"?

A. YES.

Q. AND FURTHER DOWN IN I, IT SAYS, "81 PATIENTS WERE REPORTED

FROM APRIL 1ST, 2015 THROUGH 9/16/15."

DO YOU SEE THAT LANGUAGE?

A. YES.

Q. AND WHAT WAS THE THRUST OF THE DEFICIENCY AS YOU UNDERSTOOD IT THAT WAS BEING BROUGHT TO YOUR ATTENTION?

A. WHAT IS BEING REFERENCED HERE IS THAT PATIENT RESULTS WERE RECORDED WHEN QUALITY CONTROLS WERE NOT RECORDED.

Q. AND EXPLAIN WHY THAT'S, EXPLAIN WHY THAT'S AN ISSUE.

A. QUALITY CONTROL MUST BE RUN DAILY WHEN PATIENT TEST RESULTS ARE BEING RUN ON ANY ASSAY.

Q. SO IF YOU RUN QUALITY CONTROL AND YOU FAIL QUALITY CONTROL FOR WHATEVER REASON, YOU SHOULDN'T BE REPORTING A TEST?

A. THAT'S RIGHT.

Q. AND IS THIS LISTING EXAMPLES OF WHERE IT APPEARED THAT THERANOS WAS RUNNING TESTS AFTER NOT PASSING QUALITY CONTROL?

A. YES.

MR. WADE: YOUR HONOR, MOVE TO STRIKE. IT'S BEYOND THE SCOPE OF WHAT THE EVIDENCE IS OFFERED FOR.

THE COURT: YOU CAN ASK THAT IN A DIFFERENT WAY. I'LL SUSTAIN THE OBJECTION AND STRIKE THAT ANSWER.

BY MR. LEACH:

Q. AS PART OF YOUR WORK, DR. DAS, DID YOU INVESTIGATE WHETHER THERE WERE INSTANCES WHERE THERANOS REPORTED PATIENT RESULTS AFTER NOT PASSING QUALITY CONTROL?

A. YES.

03:42PM Q. AND DID YOU FIND EXAMPLES OF THAT RELATING TO PT INR?
03:42PM A. YES.
03:42PM MR. WADE: 702, YOUR HONOR.
03:42PM THE COURT: OVERRULED.
03:42PM BY MR. LEACH:
03:42PM Q. YOU FOUND EXAMPLES OF THAT?
03:42PM A. YES.
03:42PM Q. DID YOU ALSO -- LOOKING DOWN AT PARAGRAPH 2, DO YOU SEE
03:42PM THAT THE FINDING HERE IS BASED ON A REVIEW OF THE QUALITY
03:42PM CONTROL PROCEDURE, QC RECORDS, AND RAW DATA FROM PATIENT TEST
03:43PM RUNS AND INTERVIEW WITH THE GENERAL SUPERVISOR, THE LABORATORY
03:43PM FAILED TO ENSURE THAT THE QC WAS ACCEPTABLE FOR THE TPS SYSTEM,
03:43PM OR THERANOS PROPRIETARY SYSTEM, PRIOR TO REPORTING PATIENT TEST
03:43PM RESULTS.
03:43PM DO YOU SEE THAT?
03:43PM A. YES.
03:43PM Q. IN YOUR MIND, WAS THIS RAISING A SIMILAR ISSUE WITH THE
03:43PM EDISONS THAT WAS RAISED WITH RESPECT TO PT INR?
03:43PM A. YES.
03:43PM MR. WADE: 702, YOUR HONOR.
03:43PM THE COURT: OVERRULED.
03:43PM BY MR. LEACH:
03:43PM Q. AND DID YOU INVESTIGATE WHETHER THERE WERE INSTANCES WHERE
03:43PM THERANOS REPORTED PATIENT RESULTS FROM THE EDISON DEVICE AFTER
03:43PM FAILING QUALITY CONTROL?

CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

Irene Rodriguez

IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076

Lee-Anne Shortridge

LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: NOVEMBER 9, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 31
ELIZABETH A. HOLMES,	)	NOVEMBER 10, 2021
DEFENDANT.	)	PAGES 5873 - 6145

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF:
UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
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OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:
IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

10:05AM ALSO, YOU CAN LOOK AT WHAT YOU WERE DESCRIBING, THE DISTRIBUTIONS OF ABNORMALS VERSUS NORMALS, AND GET A SENSE OF ANY SORT OF IMPRECISION IN THE ASSAY.

THERE'S VARIOUS WAYS TO LOOK AT THESE METRICS. BUT, YES IN GENERAL.

Q. SO YOU ESSENTIALLY PLOT ALL OF THE RESULTS FOR THE PATIENTS AND SORT OF LOOK AT AND ANALYZE THE DATA AND CONSIDER WHETHER YOU CAN INFER ANYTHING FROM ALL OF THE RESULTS FOR THAT PARTICULAR ASSAY?

A. TO SOME EXTENT, YES. WE MAKE CALCULATIONS BASED ON THE ENTIRE DATA SET AND LOOK AT IT IN CHUNKS. BUT, BUT OVERALL, YES.

Q. OKAY. AND THESE, THESE THREE BUCKETS THAT YOU'RE TALKING ABOUT, THIS IS A PRETTY SOPHISTICATED ANALYSIS; IS THAT FAIR?

A. YES.

Q. AND IT REQUIRED THE EXTRACTION OF A LOT OF DATA; RIGHT?

A. YES.

Q. AND IT REQUIRED THE CONSIDERATION AND ANALYSIS OF A LOT OF THAT DATA IN ORDER TO INFORM YOUR VIEWS; RIGHT?

A. YES.

Q. THIS IS NOT SOMETHING THAT IN YOUR VIEW SOMEONE WITHOUT KNOWLEDGE AND TRAINING WOULD BE IN A POSITION TO DO; IS THAT FAIR?

A. CORRECT.

Q. OKAY. AND AS A RESULT OF THAT COMBINATION OF INFORMATION,

10:27AM A. YES, I WAS USING THAT AS AN EXAMPLE.
10:27AM Q. AND MANY OF THE ANALYSES THAT YOU WERE DOING WERE PRETTY
10:28AM TECHNICAL IN NATURE; RIGHT?
10:28AM A. YES.
10:28AM Q. AND MS. HOLMES'S DIDN'T HAVE THAT SORT OF TECHNICAL
10:28AM BACKGROUND; RIGHT?
10:28AM A. YES.
10:28AM Q. AND SO YOU WERE TRYING -- AND SHE HAD NOT SUPERVISED THE
10:28AM LAB PREVIOUSLY TO YOUR KNOWLEDGE; RIGHT?
10:28AM A. CORRECT.
10:28AM Q. AND SO YOU WERE TRYING TO KIND OF BRIEF HER IN ON SOME OF
10:28AM THESE CONCEPTS AND EXPLAIN TO HER WHY YOU CAME TO THE VIEWS
10:28AM THAT YOU CAME TO; IS THAT FAIR?
10:28AM A. YES.
10:28AM Q. AND SO WHILE DOING THAT, IS IT FAIR TO SAY THAT IN SOME
10:28AM WAY YOU WERE DESCRIBING, OR TRYING TO DESCRIBE, THESE THREE
10:28AM BUCKETS AND HOW YOUR VIEWS WERE INFORMED?
10:28AM A. YES.
10:28AM Q. AND YOU USED, AS AN EXAMPLE OF THAT, THE PSA ASSAY TO NOTE
10:28AM THAT PSA WAS DETECTED IN SOME FEMALE PATIENTS, WHICH WAS
10:28AM UNUSUAL; RIGHT?
10:28AM A. YES.
10:28AM Q. AND DID YOU COME TO UNDERSTAND THAT MS. HOLMES HAD
10:29AM PROVIDED SOME KIND OF A STUDY BY ANOTHER ADVISOR THAT SUGGESTED
10:29AM THAT PSA COULD SOMETIMES BE DETECTED IN FEMALES?

11:59AM A. I DON'T RECALL THE SPECIFIC OCCASIONS.
11:59AM Q. OKAY. WELL, LET'S LOOK AT 10629.
11:59AM A. OKAY.
11:59AM Q. DOES THIS REFRESH YOUR RECOLLECTION OF MS. HOLMES ASKING YOU TO PERFORM A REVIEW OF A STATEMENT THAT WAS GOING TO BE PROVIDED TO MAKE SURE THAT IT WAS ACCURATE?
11:59AM A. YES.
11:59AM Q. AND THIS IS IN THE -- YOU RECALL HER DOING THAT IN LATE MARCH OF 2016?
11:59AM A. YES, IT APPEARS SO.
12:00PM Q. OKAY. I'D LIKE TO TALK A LITTLE MORE ABOUT SOME OTHER REFORMS THAT YOU WERE WORKING ON WITHIN THE LAB DURING YOUR TENURE AT THERANOS.
12:00PM IF WE CAN GO TO 13333. THAT'S ONE 1, FOUR 3'S.
12:00PM A. YES.
12:00PM Q. DO YOU RECALL THAT THERE WERE SOME ISSUES THAT AROSE IN CONNECTION WITH -- OR ISSUES THAT YOU DISCOVERED IN CONNECTION WITH REVIEWING THE WORK OF THE BUGS LAB?
12:01PM A. YES.
12:01PM Q. AND FOR THE BENEFIT OF THE JURY, WHAT IS THE BUGS LAB?
12:01PM A. IT WAS OUR CODE NAME FOR THE MICROBIOLOGY LAB IN NEWARK.
12:01PM Q. OKAY. AND JUST GIVE US A SENSE OF WHAT THE MICROBIOLOGY LAB WAS AND HOW IT DIFFERED FROM OTHER LABS.
12:01PM A. IT DIFFERED BY THE TYPE OF TESTING. SO THIS TYPE OF LABORATORY IS INVOLVED IN IDENTIFYING INFECTIOUS ORGANISMS.

12:01PM Q. OKAY. AND DOES THIS EMAIL RELATE TO, DOES THIS EMAIL
12:01PM RELATE TO CONCERNS THAT YOU DISCOVERED OR ISSUES YOU DISCOVERED
12:01PM IN CONNECTION WITH YOUR WORK AS LAB DIRECTOR?
12:02PM A. YES.
12:02PM MR. WADE: MOVE THE ADMISSION OF 13333.
12:02PM MR. LEACH: YOUR HONOR, I DON'T OBJECT TO THE BOTTOM
12:02PM PORTION OF THE EMAIL.
12:02PM THE TOP PORTION IS HEARSAY.
12:02PM (PAUSE IN PROCEEDINGS.)
12:02PM MR. WADE: I OFFER IT FOR THE STATE OF MIND OF
12:02PM MS. HOLMES, NOT FOR THE TRUTH.
12:02PM THE COURT: AS TO WHAT ISSUE? AS TO WHAT ISSUE?
12:02PM MR. WADE: AS TO THE REMEDIAL EFFORTS THAT WERE
12:02PM BEING MADE WITHIN THE LAB.
12:02PM MR. LEACH: IT'S AN OUT-OF-COURT STATEMENT BY A
12:02PM NONTESTIFYING WITNESS, YOUR HONOR. IT WAS THE SUBJECT OF A
12:02PM MOTION IN LIMINE.
12:02PM THE COURT: DO YOU HAVE ANY OBJECTION TO IT COMING
12:02PM IN SOLELY FOR THE STATE OF MIND FOR REMEDIAL ISSUES AT THIS
12:03PM TIME?
12:03PM MR. LEACH: YES.
12:03PM THE COURT: ALL RIGHT. I'M GOING TO SUSTAIN THE
12:03PM OBJECTION.
12:03PM MR. WADE: OKAY. I'M GOING TO OFFER -- I CAN REDACT
12:03PM THAT EMAIL.

12:03PM THE COURT: SURE.

12:03PM MR. WADE: COULD I OFFER THE BOTTOM PORTION OF THE DOCUMENT?

12:03PM THE COURT: I THINK YOU CAN DO THAT, YES.

12:03PM (DISCUSSION OFF THE RECORD WITH THE COURT AND CLERK.)

12:03PM THE COURT: COUNSEL?

12:03PM MR. WADE: MAY I PUBLISH?

12:03PM THE COURT: YES.

12:03PM (DEFENDANT'S EXHIBIT 13333, REDACTED, WAS RECEIVED IN EVIDENCE.)

12:03PM BY MR. WADE:

12:03PM Q. THIS EMAIL RELATES TO THE ISSUE WE WERE JUST DISCUSSING; IS THAT CORRECT?

12:03PM A. YES.

12:03PM Q. AND IN THIS YOU NOTE SOME GOOD NEWS LAST NIGHT REGARDING THE CAPILLARY DATA.

12:04PM DO YOU SEE THAT?

12:04PM A. YES.

12:04PM Q. AND LET'S FOCUS ON THE BOTTOM EMAIL. DO YOU SEE THAT THIS IS WHAT REFERS TO THE BUGS LAB?

12:04PM A. YES.

12:04PM Q. IT SAYS -- YOU IDENTIFIED SOME CONCERNS WITHIN THAT LAB THAT MAY JEOPARDIZE PATIENT CARE, "SO I'M BRINGING THAT ASSAY DOWN." AND IS THAT ASSAY REFERRING TO HIV?

12:04PM A. THAT IS.

12:04PM Q. OKAY. AND THEN YOU NOTED, "AS WELL AS ALL OTHERS IN THE BUGS LAB."

CORRECT?

A. YES.

Q. "AS THERE'S NO REASON TO GO ASSAY BY ASSAY IN OUR LOOK BACK AFTER UNCOVERING SUCH ISSUES."

RIGHT?

A. YES.

Q. AND IS THAT FAIR TO SAY, THAT YOU WERE EFFECTIVELY SHUTTING DOWN THE BUGS LAB?

A. YES.

Q. AND THAT'S BECAUSE, AS YOU WERE TURNING OVER THOSE ROCKS, YOU CAME TO THE VIEW THAT THAT'S WHAT NEEDED TO BE DONE HERE; RIGHT?

A. YES.

Q. AND WAS MS. HOLMES FULLY SUPPORTIVE OF YOUR DECISION TO DO THAT?

A. YES.

Q. WAS TURNING OVER THOSE ROCKS AND FINDING THOSE ISSUES EXACTLY WHAT SHE WANTED YOU TO DO WHEN SHE HIRED YOU?

MR. LEACH: OBJECTION. FOUNDATION.

BY MR. WADE:

Q. DID YOU UNDERSTAND --

THE COURT: THIS IS A NEW QUESTION?

MR. WADE: YEAH. I'LL WITHDRAW THE QUESTION.

CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

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Irene Rodriguez

IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076

Lee-Anne Shortridge

LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: NOVEMBER 10, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 34
ELIZABETH A. HOLMES,	)	NOVEMBER 17, 2021
DEFENDANT.	)	PAGES 6574 - 6779

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF:
UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
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(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:
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CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

A. YES. I MADE A DIRECT CALL TO THE NUMBER FOR THERANOS AND ASKED IF I COULD SPEAK WITH SOMEONE WORKING IN A LAB WHO COULD EXPLAIN TO ME HOW THIS IS POSSIBLE.

Q. AND HOW SOON AFTER RECEIVING THESE RESULTS DID YOU CALL THE COMPANY?

A. FROM THE DAY -- IT WAS EITHER ON THE DAY THAT I RECEIVED THEM OR THE FOLLOWING DAY.

Q. SO I UNDERSTAND WE'RE TALKING ABOUT MAY 2015?

A. UH-HUH.

Q. WHAT, IF ANYTHING, DO YOU REMEMBER ABOUT THAT CONVERSATION WITH SOMEONE AT THE COMPANY?

A. I REMEMBER ASKING IF I COULD BE TRANSFERRED TO SOMEONE WHO WORKS WITH THE LAB EQUIPMENT WHO MIGHT BE ABLE TO HAVE A MORE IN-DEPTH CONVERSATION WITH ME ABOUT HOW THIS IS POSSIBLE.

SHE SAID SHE WAS A CUSTOMER SERVICE REPRESENTATIVE AND SHE COULDN'T TRANSFER ME, AND THAT WAS ABOUT IT.

I DON'T RECALL IF I ATTEMPTED TO CALL THEM BACK AGAIN, BUT I WAS QUITE EMOTIONAL AT THE TIME.

Q. AT ANY TIME TO YOUR KNOWLEDGE DID YOU SPEAK TO A SCIENTIST OR A MEDICAL PROFESSIONAL --

A. NO.

Q. -- ASSOCIATED WITH THERANOS?

A. NO.

Q. TO YOUR KNOWLEDGE, DID YOU GET A CALL BACK FROM THE COMPANY TO PROVIDE MORE INFORMATION ABOUT YOUR TEST RESULTS?

CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

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Irene Rodriguez

IRENE RODRIGUEZ, CSR, CRR
CERTIFICATE NUMBER 8076

Lee-Anne Shortridge

LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

DATED: NOVEMBER 17, 2021

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	CR-18-00258-EJD
PLAINTIFF,	)	SAN JOSE, CALIFORNIA
VS.	)	VOLUME 40
ELIZABETH A. HOLMES,	)	NOVEMBER 30, 2021
DEFENDANT.	)	PAGES 7922 - 8213

TRANSCRIPT OF TRIAL PROCEEDINGS
BEFORE THE HONORABLE EDWARD J. DAVILA
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF:
UNITED STATES ATTORNEY'S OFFICE
BY: JOHN C. BOSTIC
JEFFREY B. SCHENK
150 ALMADEN BOULEVARD, SUITE 900
SAN JOSE, CALIFORNIA 95113

BY: ROBERT S. LEACH
KELLY VOLKAR
1301 CLAY STREET, SUITE 340S
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTERS:
IRENE L. RODRIGUEZ, CSR, RMR, CRR
CERTIFICATE NUMBER 8074
LEE-ANNE SHORTRIDGE, CSR, CRR
CERTIFICATE NUMBER 9595

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY
TRANSCRIPT PRODUCED WITH COMPUTER

10:24AM Q. AND WAS THIS PART OF YOUR EFFORT TO GET MR. MURDOCH TO
10:24AM QUASH THE STORY THAT JOHN CARREYROU WAS WRITING?
10:24AM A. IT WAS PART OF MY EFFORT TO GET MR. MURDOCH TO MAKE SURE
10:24AM THAT OUR TRADE SECRETS WERE NOT PUBLISHED.
10:25AM Q. YOU KEEP INJECTING TRADE SECRETS, AND I PROMISE WE WILL
10:25AM GET TO TRADE SECRETS.
10:25AM MY QUESTION WAS, YOU TESTIFIED THAT YOU ATTEMPTED TO QUASH
10:25AM THE STORY. I'M JUST TRYING TO UNDERSTAND, IS THIS PART OF THAT
10:25AM EFFORT?
10:25AM A. NO. I THINK AT THIS POINT WE WERE NOT TRYING TO QUASH IT.
10:25AM Q. YOU WERE TRYING TO QUASH IT SOMETIME LATER?
10:25AM A. ONCE WE UNDERSTOOD THAT OUR TRADE SECRETS WERE GOING TO BE
10:25AM DISCLOSED.
10:25AM Q. WELL, LET'S LOOK AT WHAT YOU WROTE.
10:25AM YOUR HONOR, I NEED TO DISPLAY IT ON THE ELMO. I'M PUTTING
10:25AM A POST IT OVER SOMETHING THAT I DON'T THINK IS PUBLIC.
10:25AM THE COURT: ARE YOU MOVING THIS IN?
10:25AM MR. LEACH: IF I HAVE NOT MOVED IT IN, I MOVE IT IN.
10:25AM MR. DOWNEY: NO OBJECTION, YOUR HONOR.
10:25AM THE COURT: AND JUST TO BE CLEAR, THIS IS
10:25AM EXHIBIT 5704?
10:26AM MR. LEACH: YES, YOUR HONOR.
10:26AM THE COURT: ALL RIGHT. THANK YOU. IT'S ADMITTED.
10:26AM (GOVERNMENT'S EXHIBIT 5704 WAS RECEIVED IN EVIDENCE.)
10:26AM BY MR. LEACH:

CERTIFICATE OF REPORTERS

WE, THE UNDERSIGNED OFFICIAL COURT REPORTERS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

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LEE-ANNE SHORTRIDGE, CSR, CRR
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DATED: NOVEMBER 30, 2021

Exhibit 52

United States v. Elizabeth Holmes & Ramesh Balwani, CR 18-258 EJD (N.D. Cal.),
Expert Report of Stephen Master, MD, PhD, FCAP, FAACC

March 6, 2020

I. Qualifications

I received my undergraduate degree in molecular biology from Princeton University and my MD and PhD (cell and molecular biology) from the University of Pennsylvania School of Medicine. I then did a residency in Clinical Pathology at the Hospital of the University of Pennsylvania, including time serving as Chief Resident in Clinical Pathology. After completing my residency, I spent a postdoctoral year as a research associate at Penn prior to joining the faculty as Assistant Professor of Pathology and Laboratory Medicine. During my time at Penn, I was appointed Medical Director of the Endocrinology Laboratory at the Hospital of the University of Pennsylvania, and I also spent 5 years as director of the University of Pennsylvania translational core laboratory. In 2015 I moved to Cornell as a faculty member at Weill Cornell Medical Center in New York City, where I was director of the Central Laboratory and Chief of Clinical Chemistry Laboratory Services at Weill Cornell Medicine / New York Presbyterian Hospital. In 2018 I returned to Philadelphia at the Children's Hospital of Philadelphia, where I currently serve as Chief of the Division of Laboratory Medicine, Medical Director of the Michael Palmieri Laboratory for Metabolic and Advanced Diagnostics, and Associate Professor of Pathology and Laboratory Medicine at the Perelman School of Medicine, University of Pennsylvania.

I am Board Certified by the American Board of Pathology (ABP) in Clinical Pathology, and I have additional subspecialty Board Certification from ABP in Clinical Informatics. I hold an active medical license in Pennsylvania. I am a Fellow of the College of American Pathologists as well as of the Academy of the American Association for Clinical Chemistry. I serve on the Board of Editors of the journal *Clinical Chemistry*, as well being an Associate Editor of *Clinical Proteomics* and Section Editor in Clinical Chemistry for the *Archives of Pathology and Laboratory Medicine*. I have been active professionally in the American Association for Clinical Chemistry, having served on their Board of Directors for five years. I serve as a member of the Harmonization Oversight Group of the International Council for the Harmonization of Clinical Laboratory Results. I currently have over 75 publications, including original research articles, reviews, and book chapters. In addition, I have lectured extensively at a national and international level on a variety of subjects related to Clinical Chemistry, including new paradigms for quality control. Of note, I was a member of the panel that facilitated questions and answers following the Theranos presentation at the 2016 annual meeting of the American Association for Clinical Chemistry.

My CV is attached as Appendix A.

II. Scope of Assignment

I have been retained by the United States Attorney's Office for the Northern District of California to testify as an expert witness in this matter. For purposes of this report, I was asked to provide opinions on whether Theranos was market ready and able to produce accurate and reliable fingerstick results for tests such as Vitamin D, chloride, potassium, bicarbonate, HIV,

HbA1c, hCG, cholesterol, and sodium, whether Theranos adhered to normal industry standards for clinical laboratory testing from 2013-2015, and whether any lack of adherence had the potential to adversely impact test accuracy and reliability. This report is intended to summarize my opinions and my anticipated testimony. I reserve the right to supplement or revise this report or to address additional questions if asked and based on additional information received and the evidence presented at trial. My compensation is $400 per hour. This report and the opinions contained herein are based on my training in clinical pathology and chemistry, my experience as a laboratory medical director, and my knowledge of standards and best practices as established by federal regulations and by the College of American Pathologists ("CAP"). I also considered publicly available information, scholarly research, and materials produced in discovery in this case, which are identified in Appendix B.

III. Background on Blood Testing

Blood Testing: Samples

Modern blood testing in the clinical laboratory begins with collection of a patient sample. Traditionally, this is performed using a needle that punctures a vein in the arm, and this process is called venipuncture. The blood that is collected from the vein in this way is called venous blood. A second way of collecting blood involves using a sharp lancet to puncture the end of a finger or (in the case of a newborn) the heel of a foot. The blood that is collected from these sources is known as capillary blood, because it comes from the very small blood vessels known as capillaries. In certain hospital settings, blood is collected from an artery ("arterial blood"). As oxygen-filled blood travels through arteries, then into capillaries, and

the assay is "out of control". An assay that fails quality control requires some sort of intervention, whether that is recalibration of the assay, or something more significant. If an assay is found to be out of control after continuously running samples, the lab would need to determine whether the issues with the assay affected patient results that should be corrected or cancelled.

IV. Summary of Opinions

Preliminary comments

Based on the documents that I reviewed, my understanding is that there were two primary methods that Theranos employed to measure analytes from fingerstick blood samples collected in small devices ("CTNs"). First, they had developed an instrument (often referred to as "Edison", version 3.5) that performed immunoassays. Second, they used Tecan liquid handlers to dilute small samples and run them on traditional clinical chemistry analyzers obtained from other vendors (predominantly Siemens Diagnostics). Because neither of these approaches used unmodified, FDA-cleared or approved assays in an unmodified form, they are both considered laboratory-developed tests (note that I am not here taking a position on the FDA's role in regulating these laboratory-developed test, simply pointing out their classification under CLIA). There is a third class of testing that Theranos was performing using traditional venous samples on FDA-approved or cleared instruments from third-party vendors. I will not make many comments about this last class of testing, since it is identical to the testing performed in most labs in the U.S.

Appendix B : Documents Provided

39. Superseding Indictment.pdf	PANGARKAR, CHINMAY 12-11-2018_CONF_mini.pdf
COLAB-03032.pdf	THPFM0000277148.pdf
THER-AZ-00015739.pdf	THPFM0002240153-277 (1-25-2016 CMS Ltr).pdf
THER-AZ-00015752.pdf	
THER-AZ-00025873.pdf	EX_224-SEC-TX-000006861.pdf
THER-AZ-00027137.pdf	EX_203-SEC-TX-000005684.pdf
THER-AZ-00041624.pdf	EX_207-SEC-TX-000005741.pdf
THER-AZ-00044220.pdf	EX_208-SEC-TX-000005744.pdf
THER-AZ-00048696.pdf	EX_232-SEC-TX-000006992.pdf
THER-AZ-00057896.pdf	EX_263-SEC-TX-000007009.pdf
THER-AZ-00107535.pdf	EX_221-SEC-TX-000006261.pdf
THER-AZ-00107553.pdf	EX_265-SEC-TX-000007018.pdf
THER-AZ-00107599.pdf	EX_217-SEC-TX-000005787.pdf
THER-AZ-00107615.pdf	EX_201-SEC-TX-000005619.pdf
THER-AZ-00240244.pdf	EX_230-SEC-TX-000006981.pdf
THER-AZ-00258884.pdf	EX_214-SEC-TX-000005776.pdf
THER-AZ-00265965.pdf	EX_202-SEC-TX-000005683.pdf
THER-AZ-00272941.pdf	EX_220-SEC-TX-000006245.pdf
THER-AZ-00289661.pdf	EX_213-SEC-TX-000005771.pdf
THER-AZ-00289698.pdf	EX_206-SEC-TX-000005701.pdf
THER-AZ-00289809.pdf	EX_215-SEC-TX-000005783.pdf
THER-AZ-00290926.pdf	EX_212-SEC-TX-000005770.pdf
THER-AZ-00294920.pdf	EX_223-SEC-TX-000006854.pdf
THER-AZ-00326134.pdf	EX_262-SEC-TX-000007007.pdf
THER-AZ-00361651.pdf	EX_210-SEC-TX-000005749.pdf
THER-AZ-00361665.pdf	EX_226-SEC-TX-000006865.pdf
THER-AZ-00361672.pdf	EX_264-SEC-TX-000007012.pdf
THER-AZ-00361741.pdf	EX_231-SEC-TX-000006985.pdf
THER-AZ-00381746.pdf	EX_227-SEC-TX-000006955.pdf
THER-AZ-00381902.pdf	EX_211-SEC-TX-000005761.pdf
THER-AZ-00381940.pdf	EX_218-SEC-TX-000005924.pdf
THER-AZ-00381945.pdf	EX_204-SEC-TX-000005686.pdf
THER-AZ-00382007.pdf	EX_222-SEC-TX-000006850.pdf
THER-AZ-00383659.pdf	EX_267-SEC-TX-000007119.pdf
THER-AZ-00394054.pdf	EX_216-SEC-TX-000005785.pdf
THER-AZ-00567415.pdf	EX_266-SEC-TX-000007096.pdf
THER-AZ-00631426.pdf	EX_209-SEC-TX-000005748.pdf
THER-AZ-00655855.pdf	EX_261-SEC-TX-000007006.pdf
THER-AZ-00658025.pdf	EX_205-SEC-TX-000005696.pdf
THER-AZ-00748071.pdf	EX_228-SEC-TX-000006958.pdf
THER-AZ-00760817.pdf	EX_219-SEC-TX-000006234.pdf
THER-AZ-00784304.pdf	EX_225-SEC-TX-000006864.pdf

THER-AZ-00854722.pdf	EX_229-SEC-TX-000006965.pdf
THER-AZ-01032770.pdf	
THER-AZ-01241351.pdf	SEC-TX-000005499.pdf
THER-AZ-01364813.pdf	SEC-TX-000005379.pdf
THER-AZ-01371988.pdf	SEC-TX-000005256.pdf
THER-AZ-01382947.pdf	
THER-AZ-01384212.pdf	2015 4 16.pdf
THER-AZ-01384213.pdf	2014 11 24 SB concerned about redraws focus on ADVIAs.pdf
THER-AZ-01627558.pdf	2015 3 20 PT problems specific assays.pdf
THER-AZ-01643987.pdf	2014 10 7.pdf
THER-AZ-01814302.pdf	2014 2 12 only 11 assays with signed validation reports.pdf
THER-AZ-01834407.pdf	2014 10 6 TSH VitD.pdf
THER-AZ-01834457.pdf	2014 2 5 T4 T3 Testost FSH Erika doesnt feel comfortable running
THER-AZ-01834598.pdf	patient sample.pdf
THER-AZ-01964673.pdf	2014 2 26 Vit D TPSA FT4 TSH SB complain more QC work.pdf
THER-AZ-01980804.pdf	2015 8 16 A1c.pdf
THER-AZ-02178752.pdf	2013 11 30 Vit D QC controls failed.pdf
THER-AZ-02202037.pdf	2014 6 24.pdf
THER-AZ-02202444.pdf	2013 11 30 v2 Vit D.pdf
THER-AZ-02202599.pdf	2013 12 15.pdf
THER-AZ-02202656.pdf	2015 10 20.pdf
THER-AZ-02202676.pdf	2015 11 10 Suraj discourage.pdf
THER-AZ-02203176.pdf	2013 9 15 Vit D.pdf
THER-AZ-02203225.pdf	2014 4 23 HCG.pdf
THER-AZ-02219480.pdf	2014 9 20.pdf
THER-AZ-02290798.pdf	2014 2 23 Vit D SB Suraj.pdf
THER-AZ-02317961.pdf	2014 2 5 V2 T4 T3 Testost FSH Erika doesnt feel comfortable
THER-AZ-02318740.pdf	running patient sample.pdf
THER-AZ-02347548.pdf	2015 11 15.pdf
THER-AZ-02348228.pdf	2014 11 24 SB Suraj discuss Suraj becoming LD.pdf
THER-AZ-02352943.pdf	2015 1 10.pdf
THER-AZ-02447705.pdf	2014 2 21 Suraj SB transition Tyler.pdf
THER-AZ-02483587.pdf	2015 10 19.pdf
THER-AZ-02487262.pdf	2014 3 14 SB VitD looks good.pdf
THER-AZ-02502298.pdf	2014 4 13.pdf
THER-AZ-02547993.pdf	
THER-AZ-02775612.pdf	ROSENDORFF, M.D., ADAM 02-26-2019_CONF_mini.pdf
THER-AZ-03274129.pdf	MOI_ARosendorff_2016.07.22 (reduced).pdf
THER-AZ-03274555.pdf	MOI_ARosendorff_2017.06.07 (reduced).pdf
THER-AZ-03274788.pdf	MOI_ARosendorff_2018.01.12.pdf
THER-AZ-03311173.pdf	
THER-AZ-03392468.pdf	Rosendorff, Adam.pdf (Rosendorff Deposition in *Colman*)
THER-AZ-03416369.pdf	Young, Daniel.pdf (Young Deposition in *Colman*)
THER-AZ-03540517.pdf	

THER-AZ-03541775.pdf	MOI_DYoung_2017.10.26.pdf
THER-AZ-03557708.pdf	MOI_DYoung_2017.10.26 (reduced) 2 of 2.pdf
THER-AZ-03563629.pdf	MOI_DYoung_2017.12.07.pdf
THER-AZ-03563962.pdf	MOI_DYoung_2017.10.26 (reduced) 1 of 2.pdf
THER-AZ-03563981.pdf	MOI_DYoung_2017.09.25.pdf
THER-AZ-03582349.pdf	MOI_DYoung_2018.02.08.pdf
THER-AZ-03582372.pdf	
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THER-AZ-03643649.pdf	EX_241-SEC-TX-000007974.pdf
THER-AZ-03643771.pdf	EX_258-SEC-TX-000008445.pdf
THER-AZ-03644656.pdf	EX_243-SEC-TX-000007978.pdf
THER-AZ-03646400.pdf	EX_253-SEC-TX-000008080.pdf
THER-AZ-03660456.pdf	EX_249-SEC-TX-000008058.pdf
THER-AZ-03692624.pdf	EX_239-SEC-TX-000007953.pdf
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THER-AZ-03732961.pdf	EX_237-SEC-TX-000007946.pdf
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THER-AZ-03873921.pdf	THER-0278433_image.pdf
THER-AZ-03875390.pdf	SEC-USAO-EPROD-003896671_image.pdf
THER-AZ-03875496.pdf	SEC-USAO-EPROD-006037582_image.pdf
THER-AZ-03877622.pdf	SEC-USAO-EPROD-000883746_image.pdf
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THER-AZ-03971894.pdf	SEC-USAO-EPROD-006037575_image.pdf
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THER-AZ-03971955.pdf	Copy of SEC-USAO-EPROD-003208806.xlsx
THER-AZ-04008648.pdf	SEC-USAO-EPROD-000415616_image.pdf
THER-AZ-04207456.pdf	TS-0883810_image.pdf
THER-AZ-04207655.pdf	SEC-USAO-EPROD-000711204_image.pdf
THER-AZ-04210675.pdf	SEC-USAO-EPROD-000957215_image.pdf
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THER-AZ-04522841.xlsx THER-AZ-04575022.xlsx THER-AZ-04633447.pdf THER-AZ-04681461.pptx THER-AZ-04764557.xlsx THER-AZ-04795805.pdf THER-AZ-04796248.xlsx THER-AZ-04810485.pptx THER-AZ-04815984.xlsx THER-AZ-04860064.xlsx THER-AZ-04860066.xlsx THER-AZ-04865536.pdf THER-AZ-04893884.pptx THER-AZ-04961217.xlsx THER-AZ-05066959.pptx THER-AZ-05066960.xlsx THER-AZ-05066961.pdf THER-AZ-05068520.xlsx THER-AZ-05070412.xlsx THER-AZ-05070413.xlsx THER-AZ-05070414.xlsx THER-AZ-05070584.xlsx THER-AZ-05070585.xlsx THER-AZ-05070586.xlsx THER-AZ-05070608.xlsx THER-AZ-05070765.xlsm THER-AZ-05072586.xlsx THER-AZ-05072693.xlsx THER-AZ-05073103.xlsx THER-AZ-05073132.xlsx THER-AZ-05073178.xlsx THER-AZ-05170968.pptx THER-AZ-05172126.pdf THER-AZ-05181291.xlsx THER-AZ-05181295.xlsx THER-AZ-05182852.xlsx THER-AZ-05183906.xlsx THER-AZ-05183950.xlsx THER-AZ-05184000.xlsx THER-AZ-05202675.xlsx THER-AZ-05204950.xlsx THER-AZ-05310957.pptx THER-AZ-05311812.pdf THER-AZ-05320703.xlsx	

THER-AZ-05322675.ppt THER-AZ-05323298.xlsx THER-AZ-05326515.ppt THER-AZ-05338139.pdf THER-AZ-05338184.xlsx THER-AZ-05338577.xlsx THER-AZ-05342657.xlsx THER-AZ-05349952.ppt THER-AZ-05367611.xlsx THER-AZ-05370711.xlsx THER-AZ-05370939.xlsm THER-AZ-05393292.pdf THER-AZ-05413883.pdf THER-AZ-05416476.pdf THER-AZ-05416480.pdf THER-AZ-05416481.pdf THER-AZ-05416482.pdf THER-AZ-05416483.pdf THER-AZ-05416484.pdf THER-AZ-05416485.pdf THER-AZ-05416486.pdf THER-AZ-05419510.pptx THER-AZ-05466651.xlsx THER-AZ-05466703.xlsx THER-AZ-05466704.xlsx THER-AZ-05466705.xlsx THER-AZ-05467739.xlsx THER-AZ-05467740.xlsx THER-AZ-05468260.pptx THER-AZ-05582240.pdf THER-AZ-05592156.pdf THER-AZ-05651376.xlsx THER-AZ-05992921.pdf THER-AZ-05992922.pdf THER-AZ-05992928.pdf THER-AZ-05992930.pdf THER-AZ-05992936.pdf WG000368.pdf WG006132.pdf WG028234.pdf	
CMS-014053_native.pdf Select Rosendorff Emails.pdf THPFM0004201054_image.pdf	CDPH0000001_image.pdf CDPH0000062_image.pdf CDPH0000315_image.pdf

THPFM0004806442_image.pdf THPFM0004929096_image.pdf THPFM0004990549_image.pdf THPFM0005498546_image.pdf TS-0485304_image.pdf	*Kidd et al.* Evaluation of direct-to-consumer low-volume lab tests in healthy adults.pdf PFM-DEPO-00005457_image.pdf PFM-DEPO-00005888_image.pdf SEC-USAO-EPROD-000894765_image.pdf THPFM0004993048_image.pdf THPFM0004993049.xlsx THPFM0004993050.xlsx US-FDA-0015694_image.pdf US-FDA-0015698_image.pdf US-FDA-0015842_image.pdf US-FDA-0015864_image.pdf US-FDA-0015956_image.pdf US-FDA-0015971_image.pdf US-FDA-0024046_image.pdf US-FDA-0024585_image.pdf US-FDA-0024744_image.pdf US-FDA-0024759_image.pdf US-FDA-0024797_image.pdf US-FDA-0024812_image.pdf US-FDA-0024827_image.pdf US-FDA-0030621_image.pdf US-FDA-0033540_image.pdf US-FDA-0033542_image.pdf US-FDA-0033547_image.pdf US-FDA-0033809_image.pdf US-FDA-0034774_image.pdf US-FDA-0037189_image.pdf
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THPFM0001558414_image.pdf THPFM0002371824_image.pdf THPFM0003603101_image.pdf THPFM0003866605_image.pdf THPFM0004228061_image.pdf THPFM0004363242_image.pdf THER-0298217_image.pdf THER-2395701_image.pdf THER-2395709_image.pdf THER-2396974_image.pdf THPFM0004222310_image.pdf THPFM0004222311_image.pdf	SEC-USAO-EPROD-001212700_image.pdf SEC-USAO-EPROD-001215565_image.pdf SEC-USAO-EPROD-001215924_image.pdf SEC-USAO-EPROD-001215931_image.pdf
SEC-641605.xlsx	SEC-USAO-EPROD-000516535_image.pdf SEC-USAO-EPROD-000641192_image.pdf BENNETT – CONFIDENTIAL PURSUANT TO PROTECTIVE ORDER129MINI.pdf (Bennett deposition in *SEC v. Balwani*) YAMAMOTO – MINI.pdf (Yamamoto deposition in *SEC v. Balwani*)

Additional documents and sources consulted:

Video recording of AACC 2016 Theranos presentation
cms.gov
www.westgard.com

Exhibit 53

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Western Division of Survey and Certification
San Francisco Regional Office
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

CENTERS FOR MEDICARE & MEDICAID SERVICES

Refer to: WDSC- GKY

IMPORTANT NOTICE – PLEASE READ CAREFULLY

January 25, 2016

Sunil Dhawan, M.D., Director
Theranos, Inc.
7333 Gateway Boulevard
Newark, CA 94560

CLIA Number: 05D2025714

RE: CONDITION LEVEL DEFICIENCIES – IMMEDIATE JEOPARDY

Dear Dr. Dhawan:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42 CFR 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Centers for Medicare & Medicaid Services (CMS) conducted a CLIA recertification and complaint survey of the laboratory. The onsite survey was completed on November 20, 2015. However, the survey concluded with the receipt of critical information received from the laboratory on December 23, 2015. As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. In addition, based on the Condition-level requirement at 42 C.F.R. § 493.1215, Hematology, it was determined that the deficient practices of the laboratory pose immediate jeopardy to patient health and safety. (Immediate jeopardy is defined by the CLIA regulations as a situation in which immediate corrective action is necessary because the laboratory's non-compliance with one or more Condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public.) Specifically, the following Conditions were not met:

D5024: 42 C.F.R. § 493.1215	Condition: Hematology;
D5400: 42 C.F.R. § 493.1250	Condition: Analytic systems;
D6076: 42 C.F.R. § 493.1441	Condition: Laboratories performing high complexity testing; laboratory director;
D6108: 42 C.F.R. § 493.1447	Condition: Laboratories performing high complexity testing; technical supervisor; and,

D6168: 42 C.F.R. § 493.1487 — Condition: Laboratories performing high complexity testing; testing personnel.

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

When a laboratory's deficiencies pose immediate jeopardy, CMS requires the laboratory to take immediate action to remove the jeopardy and come into Condition-level compliance. Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program.

The laboratory has 10 CALENDAR DAYS from the date of receipt of this notice to provide CMS' Central Office and San Francisco Regional Office with a credible allegation of compliance and acceptable evidence of correction documenting that the immediate jeopardy has been removed and that action has been taken to correct all of the Condition-level deficiencies in question.

Please document the laboratory's allegation of compliance using the enclosed Form CMS-2567, Statement of Deficiencies, in the columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed Form CMS-2567 documented with a credible allegation of compliance WITHIN 10 CALENDAR DAYS from the date of receipt of this notice. You must also submit documented evidence that verifies that the corrections were made. (Your allegation of compliance will be included in the public record of the inspection.)

For your information, a credible allegation of compliance is a statement or documentation that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;

2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and

3) Indicates resolution of the problems.

In addition, acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;

2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

3) What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur; and

4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If the laboratory submits a credible allegation of compliance and acceptable evidence of correction that the laboratory has removed jeopardy and come into Condition-level compliance, and we are able to verify compliance with all CLIA requirements through a follow-up survey, sanctions will not be imposed. If the laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey.

If jeopardy is not removed and the laboratory does not come into Condition-level compliance, CMS will take sanction action(s) against the laboratory's CLIA certificate. If necessary, we will advise the laboratory in writing of the sanction(s) to be imposed and/or enforcement action(s) that will be taken. These sanctions may include alternative sanctions (Civil Money Penalty of up to $10,000 per day of non-compliance pursuant to 42 C.F.R. §493.1834, Directed Plan of Correction pursuant to 42 C.F.R. § 493.1832, and/or State Onsite Monitoring pursuant to 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of the laboratory's CLIA certificate and cancellation of the laboratory's approval for Medicare payments pursuant to 42 C.F.R. § 493.1814).

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assurance measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by CMS or CMS' agents at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

Instructions for Submitting the Laboratory's Response

All responses as well as any future correspondence pertaining to this survey should be sent to:

Karen Fuller, Manager
State Oversight and CLIA Branch
Division of Survey and Certification
Centers for Medicare & Medicaid Services
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

A copy of any response the laboratory makes to CMS' San Francisco Regional Office must also be sent to CMS' Central Office at the following address:

Division of Laboratory Services
Survey and Certification Group (SCG)
Center for Clinical Standards and Quality (CCSQ)
Centers for Medicare & Medicaid Services
7500 Security Blvd – Mail Stop C2-21-16
Baltimore, MD 21244
Attention: Sarah Bennett

If you have questions regarding this letter, please contact Gary Yamamoto of my staff at (415) 744-3738.

Sincerely,

Karen Fuller

Karen Fuller, Manager
State Oversight and CLIA Branch
Division of Survey and Certification

Enclosure: Form CMS-2567, Statement of Deficiencies

cc: California Department of Public Health, Laboratory Field Services

CMS, Central Office

PRINTED: 01/25/2016
FORM APPROVED
OMB NO. 0938-0391

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D2094	493.841(e) ROUTINE CHEMISTRY (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documentation and interview with the General Supervisor (GS), the laboratory failed to investigate and document the investation of ungraded alkaline phosphatase (ALP) PT results for the 3rd event of 2014. Findings include: a. The laboratory was enrolled with the College of American Pathologists (CAP) PT program for ALP for the 3rd event 2014. b. The CAP results showed that five of five samples (CHM-06 through CHM-10) were ungraded with a code [20]. c. There was no documenation that the ungraded ALP results had been investigated. d. The general supervisor stated that the Quality Control/Quality Assurance (QC/QA) Manager was responsible for investigating ungraded PT results. e. The QC/QA Manger confirmed on 11/18/15 that an investigation was not done or	D2094		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5403	Continued From page 10 procedure record review on November 19, 2015, the laboratory failed to have a procedure manual that included the corrective action to take when calibration or quality control results failed to meet the laboratory's criteria for acceptability. Findings included: a. It was the practice of the laboratory to test patient venous complete blood counts (CBC) specimens using a Siemens Advia 2120i instrument. b. In the laboratory's procedure titled "SOP Advia 2120i Operation and Maintenance," there was no written protocol for the corrective action to be taken when calibration or quality control results failed to meet the laboratory's criteria for acceptability. c. Between February 2015 and September 21, 2015, the laboratory performed and reported 2,395 patient CBC test results using the Advia 2120i. 2. Based on review of the quality control (QC) procedure for the Edison 3.5 Theranos System and documentation provided by the laboratory, the laboratory failed to have a procedure for QC prior to 5/15/2014. Findings include: a. CL SOP-15026 Revision A, "Edison 3.5 Theranos System Daily QC Procedure" revealed an effective date of 5/15/2014. b. A chart provided by the laboratory indicated that eight of twelve analytes run on the above system were put into use for patient testing prior to 5/15/2014. The initial use dates of the eight analytes ranged from 11/6/2013 through	D5403		

Exhibit 54

UNITED STATES DISTRICT COURT

FOR THE

NORTHERN DISTRICT OF CALIFORNIA

SECURITIES AND EXCHANGE
COMMISSION,

CERTIFIED COPY

Plaintiff,

vs. CASE NO. 5:18-CV-01603-EJD

RAMESH "SUNNY" BALWANI,

Defendant.

_____/

CONFIDENTIAL PURSUANT TO PROTECTIVE ORDER

The above-captioned video deposition of SARAH BENNETT was held on Wednesday, January 29, 2020, commencing at 8:35 a.m., at the Law Offices of DLA Piper, 100 Light Street, Suite 1350, Baltimore, Maryland, before Steven Poulakos, Notary Public.

REPORTED BY: Steven Poulakos, RPR

APPEARANCES:

ON BEHALF OF THE PLAINTIFF:
SHARANYA SAI MOHAN, ESQUIRE
U.S. Department of Justice
450 Golden Gate Avenue
9th Floor
San Francisco, California 94102
Telephone: 415.436.7198
Email: sharanya.mohan@usdoj.gov

ON BEHALF OF THE PLAINTIFF:
MARC D. KATZ, ESQUIRE
U.S. Securities and Exchange Commission
Division of the Enforecement
44 Montgomery Street
Suite 2800
San Francisco, California 94104
Telephone: 415.705.8121
Email: katzma@sec.gov

APPEARANCES (Continued):

ON BEHALF OF THE PLAINTIFF:
LINDSEY L. TURNER, ESQUIRE
TAMARA CLARK, ESQUIRE (via telephone)
U.S. Department of Health and Human Services
330 Independence Avenue, S.W.
Romm 5300
Washington, D.C. 20201
Telephone: 202.205.5867
Email: lindsay.turner@hhs.gov

APPEARANCES (Continued):

ON BEHALF OF THE DEFENDANT:
STEPHEN A. CAZARES, ESQUIRE
AMANDA MARLAM McDOWELL, ESQUIRE
Orrick, Herrington & Sutcliffe, LLP
701 5th Avenue
Suite 5600
Seattle, Washington 98104
Telephone: 206.839.4300
Email: scazares@orrick.com
amcdowell@orrick.com

ALSO PRESENT: RAMESH "SUNNY" BALWANI
IOANNIS ARSENIS, THE VIDEOGRAPHER

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A What I'm showing there is the fact that I took the values, the PT values, the prothrombin time values. I put in the MNPT value that -- and the ISI numbers that Theranos was using and the calculation that I got did not match the reported result. So, in other words, the values that I got for the INR were different than what was reported by Theranos.

Q And does that mean those results reported by Theranos were inaccurate or incorrect?

A It means that they were different.

Q And for someone who is not in the lab, what does that mean to be different?

A That means the value that should have been reported was different than the value that was reported.

Q And saying it's different, is that different -- saying that the values were different than what was reported is not the same as the reported results being inaccurate?

MR. KATZ: Objection, vague.

THE WITNESS: It's not my job to determine whether a result is accurate.

BY MR. CAZARES:

Q We can continue on for number 10. At number 10, the last of the points, it says: "The

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laboratory's INR therapeutic range for most patients on -- "

A Coumadin.

Q I was going to say Coumadin -- "Coumadin/Warfarin therapy is 2 to 3. Forty-four of 81 patients had INR greater than or equal to two reported. Of the 44, 16 out of 44 had values of greater than or equal to 3 reported."

So what's the finding you're reporting there?

A What I mean by this particular statement is that because the results were biased low and of those, almost half of those -- half of those patients had results that were reported above the therapeutic range for Coumadin, I could not tell if -- what I was showing here is the number of patients that had the potential to be affected by the fact that the controls were biased low and were -- and once you get up to a certain point with Coumadin, if it's high, there's certain steps that are necessary medically to be taken for those patients.

Q And of these -- of your breakdown of these numbers, is it 16 of the 44 that had, I guess, the possibility of being affected?

A So the total universe was 81. Of those 81,

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44 had values greater than or equal to 2 and that includes the greater than or equal to 3. And then of those 44 patients, 16 of the 44 had values reported that had were greater than or equal to 3.

Q So what does that mean from a therapeutic perspective?

A That actually falls into the practice of medicine how a physician or a medical professional is going to react to those numbers. But in order for a medical professional to make an appropriate decision about Coumadin or Warfarin therapy, they need to have an accurate and reliable result.

Q You can set that aside.

MS. MOHAN: Can we go off the record?

MR. CAZARES: Sure.

THE VIDEOGRAPHER: We're going off the record. The time is 2:27 p.m.

(Deposition recessed at 2:27 p.m.)

(Deposition resumed at 2:29 p.m.)

THE VIDEOGRAPHER: We are back on the record. The time is 2:29 p.m.

(Bennett Exhibit 396 was marked for purposes of identification.)

BY MR. CAZARES:

Q Ms. Bennett, you've been handed a document

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marked 396. It appears to be a letter dated November 29, 2016, from CMS to Daniel Young, Elizabeth Holmes, Ramesh Balwani. Important notice. Please read carefully.

Do you have that in hand?

A I do.

Q Are you familiar with the document?

A I've seen it.

Q What is it?

A It is a proposed sanction letter that conditions were not met and there was immediate jeopardy.

Q And this is of the Theranos Arizona laboratory?

A Yes. That's the address in the letter.

Q And did you participate in the survey of the Theranos's Arizona lab?

A I did.

Q And did you have a partner in that survey?

A Mr. Yamamoto.

Q Okay. In the course of your survey of the Arizona lab, did you take handwritten notes in the same way as the notes that we saw earlier today relating to your survey for the California lab for Theranos?

A I believe so.

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ERRATA SHEET

Case: SEC V Ramesh "Sunny" Balwani

Witness: Sarah Bennett Date: 01/29/2020

PAGE/LINE	SHOULD READ	REASON FOR CHANGE

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REPORTER'S CERTIFICATION

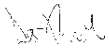
I, Steven Poulakos, Certified Shorthand Reporter in and for the State of Maryland, do hereby certify:

That the foregoing witness was by me duly sworn; that the deposition was then taken before me at the time and place herein set forth; that the testimony and proceedings were reported stenographically by me and later transcribed into typewriting under my direction; that the foregoing is a true record of the testimony and proceedings taken at that time.

I further certify that pursuant to FRCP Rule 30(e)(1), before completion of the deposition, review of the transcript [x] was [ ] was not requested.

I further certify I am neither financially interested in the action nor a relative or employee of any attorney or party to this action.

IN WITNESS WHEREOF, I have subscribed my name on this date: February 4, 2020 .



My commission expires:

August 20, 2023

Exhibit 55

From: Benedetto, Matthew
Sent: Monday, June 4, 2018 4:40 PM EDT
To: Davies, Christopher; Romeo, Mike; Mugmon, Michael; Moran, Katie
CC: Gautam, Zubin; Maali, Sahar; Smith, Robert Kingsley; Lewis, Jessica
Subject: RE: Theranos -- Summary of 5/23/18 Call with the DOJ

Redacted

From: Davies, Christopher
Sent: Thursday, May 24, 2018 5:43 AM
To: Romeo, Mike ; Mugmon, Michael ; Benedetto, Matthew ; Moran, Katie
Cc: Gautam, Zubin ; Maali, Sahar
Subject: RE: Theranos -- Summary of 5/23/18 Call with the DOJ

Redacted

From: Romeo, Mike
Sent: Wednesday, May 23, 2018 11:35 PM
To: David Taylor (dtaylor@theranos.com) <dtaylor@theranos.com>; Davies, Christopher <Christopher.Davies@wilmerhale.com>; Mugmon, Michael <Michael.Mugmon@wilmerhale.com>; Benedetto, Matthew <Matthew.Benedetto@wilmerhale.com>; Moran, Katie <Katie.Moran@wilmerhale.com>
Cc: Gautam, Zubin <Zubin.Gautam@wilmerhale.com>; Maali, Sahar <Sahar.Maali@wilmerhale.com>
Subject: Theranos -- Summary of 5/23/18 Call with the DOJ

Privileged and Confidential
Attorney-Client Communication

Hello All,

This afternoon, Michael, Matt, Katie, and I talked with Jeff Schenk and John Bostic to follow up on some open items from our call last Thursday (the 17th). Broadly, we covered the following three topics: Redacted

Redacted

Redacted 3) production of additional items requested in the DOJ's April 20th subpoena (lab data Redacted

Redacted

Redacted

5. We promised to explore options for producing additional data showing how the tests for all Theranos customers were conducted (*i.e.*, data allowing the DOJ to understand which device was used to process a given customer's test or tests).

Redacted

III. Our Production of Additional Items Requested in the DOJ's April 20th Subpoena (Lab Data) Redacted

Redacted

e. Lab data: We discussed Jeff and John's request for lab data that would show "how a given assay had been run;" in other words, what device was used to process the test a given patient received. We told Jeff and John that unfortunately, it was not feasible to simply provide a copy of the LIS database, because they would not have the experience with the system to understand how to compile the data they wanted. After a good deal of back and forth, Jeff and John asked whether it would be possible to provide them with two data compilations: (1) a table that correlates the accession number of a test ordered (this number is stored in LIS) with the name of the customer who ordered the test, and (2) a second spreadsheet which would list every test Theranos had run, together with the result and the analyzer used to run the test. Jeff and John could then match up the second table with the first table to determine how a given customer's tests were performed. We indicated that given the Company's resource constraints, we could not guarantee this could be done, but we would explore what was feasible and circle back to them on this point.

f. Finally, Jeff and John indicated they would provide us with an updated subpoena requesting patients' test results as stored in LIS which does not include the prior subpoena's carve out for HIV test results, so that we can produce the full compilation of LIS test reports we have gathered.

Redacted

Please consider the environment before printing this email.

Exhibit 56

United States Attorney
Northern District of California

1301 Clay Street, Suite 340S
Oakland, California 94612

(510) 637-3680
Fax: (510) 637-3724

October 29, 2020

By Email

Lance Wade, Esq.
Kevin Downey, Esq.
Amy Saharia, Esq.
Katie Trefz, Esq.
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, DC 20005

Re: *United States v. Holmes*, CR 18-258 EJD

Dear Counsel:

Pursuant to your requests for discovery, we write to alert you to the following information, which you may view as potential *Brady*, *Giglio*, or *Jencks* information. This supplements our letter to you dated July 9, 2019. By making these disclosures, we do not necessarily agree that this information is responsive to Rule 16, *Brady*, *Giglio*, or *Jencks*, nor do we waive any applicable privilege or protection.

* * * * *

1. Government notes of a phone call with Pete Skinner on or about January 28, 2016, state in part:

> privately held
> few SHDs
> sophisticated
> employees
> no public offering
>
> tech
> prop – h'ware, software, chem, protocol
> . . . .
> software enables TSPU and larger h'ware to hook up w/ cloud so machine can be used remotely & results viewed remotely
> big data anal.

46. On or about October 5, 2018, the ALS supervisor advised attorneys for the government and the government paralegal about issues surrounding the hard drive. She noted she had discussions with her unit, the IT department, and the LTSC. She said the drive does not contain material which could be processed in house or by the LTSC. She said the drive contains 12 BAK files totaling about 830 gigabytes. She said the .bak extension indicates that the files were most likely backup files for a Microsoft SQL database. She said if that was correct such files would be used to restore database backups on a Microsoft SQL Server. She said .bak is a common extension and without documentation of what the drive was meant to contain she could only make an educated guess that these were database backups. She said because they were archive files the size of the data could increase when restored. She said the material was not provided to the USAO in a format that can be extracted, viewed, or processed by available software. She said the LTSC's EDD [electronic data discovery] software can only digest SQL.bak files if they are under 300 mb. She suggested a possible route forward of pushing the producing party to see if the party could be persuaded to produce in a manner that can be viewed and processed in a standard way rather than an unspecified archive format the government could not access. She suggested encouraging the producing party to consider handing over its physical SQL server and setting it up in a workroom. She suggested checking with the FBI or other agencies to see if they have resources that can process large SQL database archives. She suggested identifying a vendor who could process the material and noted the data size and labor cost could be staggering. She offered to set up a call or meeting to discuss the issues further.

47. On or about October 30, 2018, the government paralegal advised the ALS supervisor she had met with attorneys for the government and the group decided to pursue the options of pushing the producing party to see if it could be persuaded to produce in a manner that can be viewed and processed in a standard way rather than an unspecified archive format the government could not access and checking with the FBI or other agencies to see if they have resources that can process large SQL database archives. The government paralegal also advised the ALS supervisor to return the hard drive when she had a chance. Around that time, the ALS supervisor did so. The hard drive remained in the possession of the government paralegal until around the spring of 2020.

48. In approximately October and November of 2020, counsel for the government was in contact with counsel for the assignee at the Dorsey law firm on a variety of topics. During those discussions, government counsel noted that the government had been unable to access the copy of the LIS database produced by Theranos. Assignee counsel expressed a lack of surprise that the government was having difficulty accessing the database, and offered to investigate whether the assignee had the database in a different form that would facilitate the government's access. During a subsequent conversation, assignee counsel reported back to the government that it had been unable to locate an alternative version of the LIS database that would allow access. Assignee counsel also informed government counsel that the LIS database was encrypted and that the assignee lacked the means to decrypt it. Assignee counsel opined that Sunny Balwani would likely be able to decrypt the database, but could not identify anyone else who they thought could accomplish the task.

49. On or about January 14, 2019, the government paralegal advised attorneys for the government that ALS had tried to process the hard drive but does not have the software to process the discovery and proposed possible options of producing a native version, involving the

Very truly yours,

STEPHANIE M. HINDS
Attorney for the United States,
Acting Under Authority Conferred
By 28 U.S.C. § 515

/s Robert S. Leach

ROBERT S. LEACH
JEFFREY SCHENK
JOHN C. BOSTIC
VANESSA BAEHR-JONES
Assistant United States Attorneys

cc Jeff Coopersmith, Esq. (by email)

Exhibit 57

Excerpts of Trial Testimony of Dr. Kingshuk Das

Tr.	Expert Subject	Excerpt
5817	Statistical analysis	Q: And what is a standard deviation? A: Would you like the more technical definition? Q: I'd like the less technical definition if you could. A: It's, in general, an estimate of the spread of a data set, how widely the values vary. … In laboratory parlance, we use it to estimate precision.
5818	CMS response	Q: And did you and your team also review the data that is listed here on this form? A: Yes. Q: And did you review an even broader universe of QC data in order to respond to the CMS report? A: We did. Q: And is this—is the finding listed here consistent with what you reviewed in your review of data? **MR. WADE: Your Honor, 702 on this issue, particularly given the purpose that this evidence has been offered.** **THE COURT: Mr. Leach, I think you're on the margins of a 702 area, so let me ask you to rephrase your question.**
5819	CMS response	Q: At any point did you tell CMS that the company disagreed with this particular finding? A: No, I don't believe we did. Q: Okay. And why not? A: These findings— **MR. WADE: Your Honor, again, 702. We're just using reverse instead of forward.** **THE COURT: I understand. I think you're asking for an opinion that falls under 702 the way the question is formed, so I'll sustain the objection.** Q: But you never said to anybody at CMS, "I disagree with this finding"? A: I don't recall saying that or writing that.
5820	Statistical analysis	Q: And as lab director, is it desirable or undesirable to have a CV of greater than 15 percent?

		A: That would be undesirable. Q: This says, "Overall 29 percent of QC samples on all tests on all devices had values greater than 2 SD's." … And what did you understand that to mean? A: That—I understand that to mean that 15 percent of the values were violating the 2 SD rule, which is a common quality control rule.
5821	CMS response	Q: Do you see where it says, "In February of 2015, the data"—oh, before I leave G, did you ever tell CMS that you disagreed with this finding in F? **MR. WADE: Your Honor, I'm going to object on 702 grounds to this as well.** **THE COURT: Overruled. You can answer the question.** A: No, I do not recall that.
5822	CMS response	Q: And then i[t] says, "In April the data revealed the following tests, showed percentage of QC samples with more than 15 percent of values greater than 2 SD, SHBG," and then there's a list of assays continuing on to page 57. … At any point in time did you tell CMS that you disagreed with this finding? A: No, I don't recall doing so.
5823	Assay results	Q: And did you give Ms. Holmes a particular reason why you thought the Edison was prone to erroneous results? A: Yes. In reviewing the data, [the PSA test] ended up being an easily digestible example of the Edison's errors [in] that I recall quite a few female patients returning PSA results, which would be highly unlikely. Q: Why was that a red flag to you? A: Because females should generally not have PSA detectable. It should only be detected in males.
5825	CMS response	Q: And in the course of… preparing these patient impact assessments, were you—did you view yourself as fulfilling your obligations as the CLIA lab director? A: Yes, I did. Q: And why did you feel that was part of your obligations as the CLIA lab director?

		A: That's not only a regulatory obligation but a professional one and an ethical one as well.
5826	CMS response	Q: In the course of responding to the CMS 2567, did you, as the laboratory, detect errors in the patient reported results? A: We did. Q: And did you feel that you were required to take certain action pursuant to this CLIA regulation and your professional responsibilities? A: Yes, that's correct.
5829	CMS response	Q: [The response] then reads, "Upon review of that [prior] response, including the entirety of the prior analysis of TPS 3.5 QC data and patient test result distributions for all analytes during the time period examined, the laboratory made note of poor QC performance throughout." Is that an accurate statement? A: That is an accurate statement.
5830	CMS response	Q: It then says, "Therefore, laboratory conducted an expanded retrospective analysis for 2014 and 2015 QC data." What does that mean? A: In general that means we expand the range of the QC data that we looked at because we identified issues with the original data, meaning we wanted to see how far the poor performance extended.
5830–31	Quality control	Q: It then says, "The laboratory noted multiple and recurrent time periods (across all analytes tested) of abrupt shifts in QC target means." What does that mean? … A: So that first part means that the average values of quality control, the targets that we were trying to reach, or that the laboratory was targeting, were being shifted unexplainedly. Q: "High rates of 1-2S QC rule failures." What is meant by "1-2S"? A: So this 1-2S actually refers to the same QC failures that the CMS inspectors were noting in that D tag. … So the 2S refers to 2 SD analogous to what is being referred to in the D tag. Q: And "QC CV's far exceeding limits for a stable testing process." What did that mean?

		A: To simplify that one a bit, it just means that there was a lot of imprecision noted. Q: And is imprecision desirable or undesirable? A: Undesirable.
5832	CMS response	Q: And "the laboratory has concluded that there is a possible patient impact for every test reported from the laboratory's TPS 3.5 instruments." Is that what you communicated to CMS? A: Yes, I believe so. Q: And was that your view at the time? A: Yes, it was.
5833	Voiding results	Q: In corrective action it reads, "The fraction of patient results truly impacted, and the nature and magnitude of any effect are unknown. Out of an abundance of caution, the laboratory has voided all patient test results reported from the TPS 3.5 instruments." … And did you, in fact, void all of the test results from the Edison device from the 2014, 2015 time period? A: Yes, we did so.
5833–34	Voiding results	Q: Describe the substance of what was said [to Ms. Holmes]? A: I described our rationale for voiding these tests which relied on some of the things that we discussed earlier, which was the validation data as well as the QC data that is referenced here, and it was—I can't remember all of the constituents at that meeting, but I tried to present it in a more understandable format. So I described the issue in terms of the validation data in describing that these instruments apparently were not performing from the very beginning. … Q: And did you think it was a complete explanation to describe it as just a quality control issue? A: No, sir. Q: How come? A: Because the validation data had no bearing on the quality control or quality assurance program.
5835	Voiding results	Q: Did you ever recommend that testing be resumed in the CLIA lab? A: No.

		Q: And why was that? A: I found these instruments to be unsuitable for clinical use.
5847–48	Quality control	Q: And the QC level 1 and level 3, what did you understand those to refer to? A: Those are different levels of the respective test QC, in this case vitamin B12. Q: And can you—and what is the purpose of different levels? A: A laboratory is required to run multiple levels for every quantitative test, so— Q: So a high level, a low level, something in between? A: Correct. Q: Okay. And this says the QC level 1 and 3 were 34.3 and 48.5 percent. What was—what did you understand that to mean? A: It appears they're referencing those particular levels for those QC. Q: And are these desirable levels of QC or undesirable levels of QC? A: Those would be undesirable.
5849	CMS response	Q: Dr. Das, did you understand these to be additional examples of high CV in QC testing on devices within the CLIA lab? A: Yes. Q: And similar to what we looked at before, are these issues that you investigated as part of your work? A: Yes. Q: And at any point in time, did you disagree with what CMS was finding here? A: No.
5851	Voiding results	Q: And did Theranos ultimately void all of the tests on the Edison device? A: Yes.
5853–54	CMS response	Q: And did—in response to the 2567, did you ultimately determine to—that there were errors in the PT INR test? A: Yes. Q: And describe those for us, please. A: Yes. There were actually a variety of findings. One of them

was errors in the calculation of the values that has to do with each lot that is used for this assay on the Siemens instrument. There were also deviations in the patient test result distributions, as well as quality control issues.
Q: And did—
MR. WADE: Your Honor, pardon me. Just move to strike on 702 grounds.
THE COURT: I'm going to sustain the objection. And that last portion is stricken, ladies and gentlemen.
Q: Did you—in communicating to CMS, did you describe the bases—did you tell CMS that Theranos was voiding PT INR tests?
A: Yes.
Q: And did you explain to them why Theranos was doing that?
A: Yes.
Q: What did you tell CMS?
A: I do not recall the exact language, but it reflected the inaccurate calculations, as well as quality control issues and inaccuracies reflected in the patient test result distributions.

5855–57 Quality control

Q: So if you run quality control and you fail quality control for whatever reason, you shouldn't be reporting a test?
A: That's right.
Q: And is this listing examples of where it appeared that Theranos was running tests after not passing quality control?
A: Yes.
MR. WADE: Your Honor, move to strike. It's beyond the scope of what the evidence is offered for.
THE COURT: You can ask that in a different way. I'll sustain the objection and strike that answer.
Q: As part of your work, Dr. Das, did you investigate whether there were instances where Theranos reported patient results after not passing quality control?
A: Yes.
Q: And did you find examples of that relating to PT INR?
A: Yes.
MR. WADE: 702, your Honor.
THE COURT: Overruled.
Q: You found examples of that?

A: Yes.
Q: Did you also—looking down at paragraph 2, do you see that the finding here is based on a review of the quality control procedure, QC records, and raw data from patient test runs and interview and the general supervisor, the laboratory failed to ensure that the QC was acceptable for the TPS system, or Theranos proprietary system, prior to reporting patient test results. Do you see that?
A: Yes.
Q: In your mind, was this raising a similar issue with the Edisons that was raised with respect to PT INR?
A: Yes.
MR. WADE: 702, your Honor.
THE COURT: Overruled.
Q: And did you investigate whether there were instances where Theranos reported patient results from the Edison device after failing quality control?
A: Yes.
Q: And did you find instances of that?
A: Yes.
Q: More than one?
A: Yes.
Q: And was that an issue?
A: Yes.
Q: Why is that?
A: For the reasons I delineated earlier. It's required to do quality control on every day that patient test results are run.

5857–58 Quality control

Q: Do you see where it says in D, "QC records for sex hormone binding globulin, showed that on device E 1025, QC level 2'S, 24 expiration was on 8/14/14 at 18:54 and was not run again until 8/15/14. Patient data showed that patient session," and there's a number, "was run on 8/14/14 at 19:09." …
Q: And in your mind, did you understand this—was this CMS raising the issue of Theranos reporting patient results for this particular assay after failing quality control?
A: Yes.
Q: And that's an issue that you investigated as well?

		A: Yes. Q: And you found instances where that happened? A: Yes.
5858	Quality control	Q: And what is a 10X warning message? A: That is referring to a quality control failure where the quality control results lie on one side of the mean either above or below ten times consecutively. Q: And in the course of your work, did you see instances where Theranos continued to report patient results after this 10X warning had come up? A: Yes.
5859	Quality control	Q: And it's been a while since we've heard that term, but what is a Levey-Jennings chart? A: It's also known as a control chart. It's just a way to chart quality control values over time with respect to the expected mean and standard deviations. Q: And at any point in time did you communicate to CMS that you disagreed with this finding? A: No. Q: That would be true of the findings in P and Q related to the Lev[e]y-Jennings charts? A: Yes.
6023	CMS response	Q: And in response to the 2567, you reviewed not just the quality control data that was listed in the CMS report, but a broader universe of data. Is that fair? A: Yes. Q: And what was the reason for doing that? A: That was to identify the extent of the deficiency. Q: Okay. And after that broader review, did you view the instances that were listed by CMS as representative samples? A: Yes. Q: Those didn't seem out of—unusual in the sense of being one offs or out of the ordinary? A: Outliers? Is that correct? Q: We've used that term in some other contexts. I just want to make sure if what was reported in CMS was representative of

		what you saw in your broader review. A: Yes.
6024–25	Quality control	Q: And is quality control, like, the alarm bell to assess whether a particular assay is working or not working as it's supposed to? A: Yes. Q: Okay. And based on your review of the broader universe of QC data, were alarm bells going off? A: Yes.
6026–27	Quality control	Q: You wrote, "I had a chance to touch base with Tina and Daniel the other day to get details on the updated patient impact assessments, and I've decided to take a more conservative approach." Is that in the context of these assays run on the Siemens Advia? A: Yes. Q: And just explain for us what you meant by that. A: Regarding the prior email, there was an approach outlined that I disagreed with. Q: And what was the approach you disagreed with? A: If I remember correctly, they were proposing a more liberal approach that would require multiple analytes to be, quote-unquote, abnormal in order to trigger voiding or corrections, and I disagreed with that assertion. Q: And you wanted to look at it analyte by analyte; is that fair? A: Yes, that would be the correct way to do it. Q: And when you voided tests on the Edison 3.5 device, were you being conservative? A: Can you clarify, please. Q: Did you feel like you were being conservative? A: I was just following the data.
6028	Quality control	Q: And I think you were then shown some questions or asked some questions about some additional assays that had been run on the modified Siemens machine, and you were asked were you comfortable with the data, and your answer was at that point in time. Do you recall that testimony? A: Yes.

		Q: And what did you mean by “at that point in time”? A: We subsequently turned over more rocks and stones.
6029	Voiding results	Q: Did you get pushback from Ms. Holmes about how to characterize the voiding of the tests? A: Yes. Q: Describe that pushback for us, please? A: There was a characterization for why the voiding was done, to which I disagreed. Q: And that characterization was what? A: That characterization was that the problems were due to issues with quality control and quality assurance rather than the instrument itself. Q: And that was communicated—the idea that this was just a quality systems issue was communicated to CMS; is that correct? A: Yes. Q: And you disagreed with that? A: Yes.

Exhibit 58

Message

From: Elizabeth Holmes [/O=THERANOS ORGANIZATION/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=EHOLMES]
Sent: 9/8/2015 7:04:26 PM
To: Murdoch, Rupert [ ]
Subject: FW:

Dear Rupert,

I hope all is wonderful with you and that you had a wonderful labor day. I have very much been looking forward to seeing you when you are out this way again.

For the purpose of keeping you in the loop, I wanted to share the attached documents with you, including a briefing document that was sent from David to Gerard at WSJ today in the hopes that Gerard might meet with our team. I have also attached the material Theranos has shared with WSJ (responsive to questions from John Carreyrou) since the materials I gave you in July. As I've reflected on this, I thought that were I in your shoes I would want to know/be in the loop on this one, and since you had the prior materials from July, wanted to give you the complete set. We are very much hoping that Gerard will meet with our team. If you have thoughts on that please do let me know.

Talk to you soon,

With all my very best,

Elizabeth

Exhibit 59

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DJIA 24296.79 -0.25% ▼ S&P 500 2665.66 -0.26% ▼ Nasdaq 7250.35 -0.20% ▼ U.S.10 Yr -7/32 Yield 2.980% ▼ Crude Oil 69.02 -2.42% ▼ Euro 1.1880 -0.36% ▼

THE WALL STREET JOURNAL.

THE WEEKEND INTERVIEW

Elizabeth Holmes: The Breakthrough of Instant Diagnosis

A Stanford dropout is bidding to make tests more accurate, less painful—and at a fraction of the current price.

By Joseph Rago

Updated Sept. 8, 2013 12:04 p.m. ET

Palo Alto, Calif.

"The reality within our health-care system today is that when someone you care about gets really sick, by the time you find that out it's most often too late to do anything about it. It's heartbreaking. Because in those moments, there's nothing you wouldn't do to change it, and too often you're helpless," says Elizabeth Holmes. "We're finding cancer when you have a tumor, or heart disease by virtue of the fact that you're having a heart attack."

She wants to change that.

Ms. Holmes, a 29-year-old chemical and electrical engineer and entrepreneur, dropped out of Stanford as an undergraduate after founding a life sciences company called Theranos in 2003. Her inventions, which she is discussing in detail here for the first time, could upend the industry of laboratory testing and might change the way we detect and treat disease.

Ten years ago, Ms. Holmes was working out of the basement of a group college house, a world away from her current headquarters at a rambling industrial building in a research park just off campus. The company's real estate was one of the few Theranos facts known to Silicon Valley, but one suggestive of the closely held business's potential: The space was once home to Facebook, and before that Hewlett-Packard.

The secret that hundreds of employees are now refining involves devices that automate and miniaturize more than 1,000 laboratory tests, from routine blood work to advanced genetic analyses. Theranos's processes are faster, cheaper and more accurate than the conventional methods and require only microscopic blood volumes, not vial after vial of the stuff. The experience will be revelatory to anyone familiar with current practices, which often seem like medicine by Bram Stoker.

A Theranos technician first increases blood flow to your hand by applying a wrap similar to one of those skiing pocket warmers, then uses a fingerstick to draw a few droplets of blood from the capillaries at the end of your hand. The blood wicks into a tube in a cartridge that Ms. Holmes calls a "nanotainer," which holds microliters of a sample, or about the amount of a raindrop. The nanotainer is then run through the analyzers in a Theranos laboratory. Results are usually sent back to a physician, but a full blood work-up—metabolic and immune markers, cell count, etc.—was in my inbox by the time I walked out the door. (Phew: all clear.)

It's the kind of modern, painless service that consumers rarely receive in U.S. health care, though Ms. Holmes makes the point the other way around: "We're here in Silicon Valley inside the consumer technology world . . . and what we think we're building is the first consumer health-care technology company. Patients are empowered by having better access to their own health information, and then by owning their own data."

FRED HARPER

And a Theranos clinic may be coming soon to a pharmacy near you. On Monday the company is launching a partnership with Walgreens for in-store sample-collection centers, with the first one in Palo Alto and expanding throughout California and beyond. Ms. Holmes's long-term goal is to provide Theranos services "within five miles of virtually every American home."

Diagnostics is one of those corners of the health markets that is more irrational the closer you look. Tests account for between 2% and 2.5% of health spending, but Ms. Holmes notes that they drive an estimated seven or eight of every 10 clinical decisions by physicians, with 6.8 billion lab tests annually in the U.S.

"The art of phlebotomy originated with bloodletting in 1400 B.C. and the modern clinical lab emerged in the 1960s—and it has not fundamentally evolved since then," she says. The billions of tests generally follow the same ritual: In a hospital or clinic, "you go in, sit down, they put a tourniquet on your arm, stick you with a needle, take these tubes and tubes of blood," as Ms. Holmes describes it.

The specimens are then transported, via a courier or hospital pneumatic tube, to a centralized lab, where they are manually removed from the tubes with a pipette and mixed with a chemical reagent or sent through instruments like a centrifuge or mass spectrometer. After days or weeks of waiting, your doctor finally gets the results.

One major problem, Ms. Holmes says, is that physicians rarely have "the best actionable information to make the best possible diagnosis at the time it matters." She posits a hypothetical patient whose doctor orders a test and discovers that she has a dangerously low hemoglobin count, so he puts her on an anti-anemia drug. He must order another test to find out what kind of anemia she has, and days later it turns out to be merely an iron deficiency. The best final treatment was actually "take some iron pills or eat more spinach."

Theranos's technology eliminates multiple lab trips because it can "run any combination of tests, including sets of follow-on tests," at once, very quickly, all from a single microsample. Ms. Holmes estimates that patients and doctors will receive readouts in "as little as two hours" and can even do so before an office visit based on their physician's recommendation for better, or at least less ad hoc, consultations.

Only about 62% of tests that doctors order are ultimately carried out, according to health-policy researchers at the Lewin Group. One reason tests aren't performed: not enough blood. To ensure that labs don't reject samples, several studies have documented that medical institutions sometimes collect as much as *45 times* the amount of blood from patients that conventional tests actually require.

Luckily, blood is a renewable resource, though the small Theranos sample size is a particular advance for the elderly, for whom blood draws can be agony because of collapsed veins. It's also good news for children who fear needles, and for oncology patients, whose blood is being constantly tested.

Another Theranos advance is its testing's accuracy. Ms. Holmes believes the chain of conventional laboratory custody introduces too many opportunities for error, "which is basically wherever humans are involved." The integrity of lab specimens can be contaminated if they sit too long on the bench, or if they're mistakenly processed by a tech, or by temperature, and so forth.

A 2002 review in the journal Clinical Chemistry found error estimates ranging from one out of every 33-50 tests to one of every 8,300, though the rate has likely since improved. The same sample sent to two different labs can yield two varying results, and the same lab testing the same sample twice can yield different results too.

That's because the precision of lab instruments, and their reference ranges, vary from manufacturer to manufacturer. Labs buy from different vendors and often don't calibrate the machines to each other. Certain tests may be reported with fairly wide margins of error, such as a plus-or-minus 30% of allowable error for HDL cholesterol. Ms. Holmes notes that a measurement that is essentially a 60% error range isn't very useful, especially over time, since disease itself is a progression over time.

Theranos's technology is automated, standardized, and attempts to subtract human

error from the process. It can thus achieve much lower variance ranges for a given test. Ms. Holmes says its tests have margins of "allowable error" targets less than 10%.

The medical promise of this speed and better information means catching disease in its earliest stages before the onset of symptoms. The company's analytic tools might also help realize the possibilities of truly personalized medicine, as scientists gain a better understanding of the heterogeneity of disease and how to treat individuals based on their own bodies, not large averages.

Theranos's tools may also allow doctors to analyze data "longitudinally"—to see trends, clusters and rates of change that they can't now. Medicine would ask fewer on-off, do-you-have-this-disease-or-not questions, and instead "meaningfully and powerfully answer the question of how to detect and manage these diseases early on," says Ms. Holmes.

She first funded Theranos at age 19 by cashing out an education trust that her parents set up, which allowed her to hire her first employee and rent lab space. Later rounds of funding were raised from venture capital and private equity. Once Theranos was more established, it started to earn revenue from contracts conducting pharmaceutical testing in cancer drug and other clinical trials.

A word about costs and what that investment bought, which doesn't follow the usual rules about a new medical technology. Ms. Holmes says Theranos can conduct a battery of tests for "tens of dollars," a phrase that does not exist in U.S. health care. She calls it "a watershed opportunity to change the trajectory of health costs through price transparency."

Since 1984, the Medicare Clinical Laboratory Fee Schedule has set reimbursements for 1,140 unique lab tests across 57 U.S. jurisdictions. That's 64,980 different price controls. Meanwhile, the prices that private insurers negotiate with providers are virtually trade secrets.

Theranos is committing to a half-off discount on Medicare fees. "So a test that costs $100 now, we'll do $50 or less. The quote-unquote payer community I don't think has ever seen someone walk in and say we want to bill you at less than you're willing to reimburse," she says. If this strategy succeeds in squeezing down prices—say, lowering testing as a share of total health costs to 1.5% from 2.3% now—it could save Medicare $61 billion over 10 years and Medicaid $96.1 billion, according to what Theranos calls a conservative estimate.

Ms. Holmes says her larger goal is increasing access to testing, including among the uninsured, though she might also have a market-share land grab in mind. For instance, she says Theranos will publish all its retail prices on its website. The company's X-ray of self-transparency also includes reporting its margins-of-error variations online and on test results and order forms, which few if any labs do now.

This strategy may be inviting a hell of a battle with the health industry, where the incentives are rigged against startups and the empire usually finds a way of striking back. Witness the medical-practice regulations that make medicine a cartel against competitors. Pathologists, lab scientists and technicians won't be pleased if their jobs go the way of travel agents.

Ms. Holmes declines to discuss Theranos's future plans, though one may speculate. There could be military applications in the battlefield, especially given the numerous framed American flags across the Theranos office and the presence on its corporate board of retired Gens. Jim Mattis and Gary Roughead, former Defense Secretary Bill Perry and former Secretary of State George Shultz.

The other obvious tech reality is that the devices keep shrinking, and over the last several years Theranos has been granted several patents for portable diagnosis system at the point of care. One of them even invokes—forget the iWatch—a wearable diagnostic device that would attach to the body with silicon microneedles "about the size of a human hair."

The biggest question is whether Ms. Holmes has discovered one of those often promised, more often elusive disruptive innovations designed to cut costs while improving quality. In a conversation about a year ago, Secretary Shultz said Ms. Holmes could be "the next Steve Jobs or Bill Gates."

When I put it to him again on my recent visit, he smiles slyly. "This is not the last thing she's going to invent or create."

Mr. Rago is a member of the Journal's editorial board.